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The Honorable Sherry R. Fallon
United States District Court for the District of Delaware
844 N. King Street
Wilmington, DE 19801-3555

VIA ELECTRONIC FILING

REDACTED - PUBLIC VERSION

Re: *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 23-975-RGA-SRF

Dear Judge Fallon:

Plaintiff United Therapeutics Corporation ("UTC") respectfully requests that the Court deny Liquidia's Letter Motion (D.I. 189, 200; "Letter"). Fact discovery is closed, yet Liquidia's belated motion seeks to compel UTC to collect, review, and produce myriad documents, if they even exist, cutting across at least eight custodians. UTC has already more than met its discovery obligations and has repeatedly described to Liquidia the scope of its custodial and non-custodial document collections, which were designed to find documents responsive to Liquidia's facially overbroad RFPs. Liquidia's Letter is an attempted end-run around the close of fact discovery and should be rejected.

Liquidia's motion suffers from several flaws, including its failures to show (1) diligence, (2) that UTC is "withholding" any documents, (3) relevance, or (4) that the discovery would not be unduly burdensome to UTC and would be proportional to the needs of the case.

Further, Liquidia's arguments (Letter at 3) regarding certain transcript confidentiality designations are premature, which Liquidia tacitly concedes (citing Letter Ex. 19).[1] Because Liquidia is apparently not pressing this issue in light of ongoing negotiations, UTC will not further address the matter here.

I. Liquidia's Belated Motion Should be Denied

Lack of diligence. Liquidia's lack of diligence in seeking additional documents after the close of fact discovery is glaring. Liquidia first served its Requests for Production (Nos. 1-75) on May 16, 2024, and UTC timely provided its responses and objections on June 17, 2024 (Letter Ex. 1). During the ensuing *four months* between UTC's responses and objections and Liquidia's emails on October 18 and 31 (Letter Ex. 6 & 16), not once did Liquidia identify [redacted] as a subset of documents it sought. Moreover, Liquidia did not even ask to meet and confer about [redacted] until after filing its Letter motion. Indeed, the request for production identified by Liquidia as purportedly covering these documents (RFP 38, which was not raised in D.I. 189),

[1] Liquidia incorrectly asserts that "*UTC* has designated" Dr. Faria-Urbina's transcript as "Highly Confidential." Letter at 3 (emphasis added). That designation was actually made by subpoenaed non-party Dr. Faria-Urbina, as permitted by paragraphs 2 and 39 of the Protective Order (D.I. 48).

seeks "communications between UTC and any third party" specific to treatment of PH-ILD, not [redacted]. Liquidia also failed to request communications between Rajan or Rajeev Saggar and [redacted] [2] This is despite the facts that Rajeev Saggar is a Liquidia employee and Rajan is his brother—both represented by Cooley, Liquidia's counsel.

Liquidia acts as if fact discovery has not closed. In fact, despite the Court's recent order denying Liquidia's extension of fact discovery, Liquidia *immediately* informed UTC that it again "intend[s] to address the extension of fact . . . discovery." Letter Ex. 19 at 5. Liquidia's motion and actions stand in stark contrast to the diligence requirement imposed on all parties in this circuit. *See Summy-Long v. Pennsylvania State Univ.*, 715 F. App'x 179, 184 (3d Cir. 2017) (affirming denial of a motion to compel as untimely because the movant waited "to challenge the objections and compel production of the documents, filing a motion to compel on the very last day of discovery" and "was unable to file the motion to compel discovery in a diligent manner"); *see also, e.g.*, *Genzyme Corp. v. Lupin Ltd.*, 2011 WL 2490603, at *2 (D. Md. June 21, 2011) ("During [fact discovery], Defendants had ample time to request the documents they now seek, but instead they waited until the week of the discovery deadline to make their demand . . . . When evaluating such last-minute requests for additional discovery, a district court properly declines to extend discovery . . . when [a party] had many months to make both her initial and follow-up discovery requests." (quotation omitted)).

UTC's thorough search, collection and production. Although Liquidia asserts that UTC is "withholding" documents, that is simply not the case. UTC's identification of custodians was timely (over 6 months ago), and its collection was proper, thorough, and based on the parties' disclosures of claims and defenses and guided by Liquidia's discovery requests.[3] UTC expended significant resources to collect and produce over 5,000 documents from those custodians. UTC performed an extensive search and document collection and produced relevant documents, specifically looked for the communications Liquidia now seeks, and produced them. UTC is not "withholding" the documents; it already produced what it found. *See* D.I. 193 at 3 ("Plaintiff confirmed that it reviewed and produced all responsive communications involving both individuals that were within the custodial files."). There is no reason that UTC should now need to perform an *additional* round of document collection from new custodians after the close of fact discovery.

No relevance or proportionality. Liquidia has also failed to explain how any of the documents it now seeks are relevant to its defenses and proportional to the needs of the case under Rule 26. Liquidia appears to seek (1) communications between two Saggar brothers represented by Liquidia's counsel and various UTC employees and former employees, and (2) [redacted] and, possibly, an alleged [redacted].

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[2] In UTC's view, the scope of what Liquidia seeks remains unclear. To the extent that Liquidia seeks other documents, those were not discussed on the parties' November 13 meet and confer.

[3] Liquidia also argues that UTC failed to produce Laliberte custodial documents (Letter at 2). However, UTC produced hundreds of documents that included Mr. Laliberte, a former employee. UTC also made him available for deposition on November 8. Liquidia has failed to articulate any resulting prejudice.

First, there is no relevance for communications about intravenous, subcutaneous, or oral treprostinil when the asserted claims are expressly limited to "administering by *inhalation*." D.I. 8-2 at claim 1 (emphasis added). Nor has Liquidia articulated any rationale under which the requested communications would constitute "prior art" or invalidating prior use of the claimed invention. Neither Liquidia's pleadings (D.I. 12) nor its invalidity contentions have set forth a cognizable "prior use" theory of the claimed method of improving exercise capacity sufficient to support its document request. Liquidia cites "Ex. 18 at 44" as supporting "invalidity due to prior public use of Tyvaso®," but that does not discuss prior use at all. *See* Fed. R. Civ. P. 26(b)(1) (requiring discovery to relate to a "party's claim or defense"). Indeed, it remains unclear how [redacted] s somehow public information that could impact patent validity.

Nor has Liquidia established proportionality for the communications it seeks beyond the thousands of files already produced by UTC concerning the individuals Liquidia complains about. Liquidia seeks communications between the Saggar brothers and [redacted] Three of those custodians have not worked for UTC in years [redacted]. Liquidia did not object to UTC's list of custodians last May to request that UTC add [redacted], even though it had access to both Saggar brothers. And UTC has already produced all communications located after its diligent search of Leigh Peterson's and Chunqin Deng's files. At this stage, requiring anything more of UTC is unduly burdensome and disproportional to the needs of the case.

This is not proportional to the needs of this case, especially where, as here, the communications Liquidia seeks regarding the Saggar brothers are equally as accessible to Liquidia's attorneys as they are to UTC. *See* D.I. 193 ("[C]ounsel for Defendant represents Dr. Rajan Saggar in connection with the subpoena, and documents from Dr. Rajeev Saggar were available to Defendant in his capacity as Defendant's CMO.").

Second, there is no relevance for the requested [redacted] or [redacted] Liquidia previously made clear that it was not seeking documents with personal patient information, so its recent assertion of relevance is an about-face from its position in discovery months ago. Liquidia explicitly stated that it "seeks documents responsive to these RFPs that do ***not*** include privileged patient information." Ex. A (R. Minn email dated July 31, 2024) (emphasis added). That scope is inconsistent with Liquidia's new request for [redacted] which, to the extent any relevant [redacted] exist, would be rife with "privileged patient information." To be clear, any such [redacted] are industry standard and part of an FDA program to report adverse events that happen to specific patients—in fact, [redacted]. *See* Ex. B (Tyvaso Label). Liquidia never explains why [redacted] would show invalidating use.

The testimony Liquidia cites does not make the files relevant either. [redacted] But this testimony does not indicate that [redacted]. Rather, UTC has multiple commercialized "treprostinil" drugs, including Remodulin (intravenous and subcutaneous forms)

and Orenitram (oral form).[4] There are also myriad reasons why a patient's treatment may not be "on the label"—none of which are relevant to a claim or defense in this case—such as using a dose inconsistent with the label or for a given patient. [redacted]

The closest Liquidia comes to arguing relevance is its argument that there was some ill-defined "prior art sales of Tyvaso falling within the scope of the claims—[redacted] Letter at 2. But the cited transcripts do not support the fanciful conclusion Liquidia argues; instead, they just address reimbursement and *current* (not prior art) sales. *See* Letter at 2 (citing Ex. 5 at 63:23-64:14 (Dr. Tapson explaining that PH products are expensive and his clinic nurse would handle seeking reimbursements for patients); [redacted]

Nor are the [redacted] proportional to the needs of the case. Liquidia is seeking or has already obtained related deposition testimony from its own employee and his brother (Rajeev and Rajan Saggar), at least five nonparties (Dr. Faria-Urbina, Dr. Tapson, Kevin Laliberte, Kiernan DeAngelis, and Dr. Waxman), and all three named inventors about alleged prior use. To locate the documents Liquidia seeks, if they exist, UTC would have to search all of the [redacted]. After fact discovery has closed, there is no reason to burden UTC with this additional search, collection, review and production that would require patient information redaction, all to provide at most little, and likely no, relevant information.

Liquidia also mentions a purported [redacted] Letter at 2. But there is no relevance for a [redacted]—it cannot be prior art. And if Liquidia really believed this was "highly relevant," it would have deposed UTC's corporate representative on regulatory matters, Dean Bunce, about it—but it did not. Nor did Liquidia ask Peter Smith, who was designated on a topic relating to use of Tyvaso for PH-ILD patients prior to March 12, 2021. Ex. C (UTC responses to LIQ 30(b)(6) Notice) at 5. And to the extent Dr. Saggar was even referring to an [redacted] he further admitted that [redacted] so it is not clear why Liquidia believes UTC has retained for a decade a [redacted] and Dr. Saggar himself apparently did not retain it.

II. Conclusion

For the reasons set forth above, UTC respectfully requests that the Court deny Liquidia's Letter. Moreover, Liquidia's requests regarding confidentiality designations are not ripe.

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[4] Liquidia argues that Letter Exs. 8-13 support that responsive documents were withheld, but these exhibits relate to [redacted].

Respectfully submitted,

Michael J. Flynn (#5333)
Counsel for Plaintiff
United Therapeutics Corporation

cc: Clerk of the Court
All counsel of record

From: Minn, Robert
To: Pappas, Katherine; Dykhuis, Art; jblumenfeld@morrisnichols.com; mflynn@morrisnichols.com; Carsten, Douglas; Burrowbridge, Adam; Cheng, Katherine; Rosner, Gail D
Cc: z/Liquidia v UTC 308970-201; Karen Keller; nhoeschen@shawkeller.com; Emily DiBenedetto; DG-ILD; UTCvLiquidia-Del-23cv975
Subject: RE: UTC v. Liquidia (23-975) - RFP M&C Follow-up
Date: Wednesday, July 31, 2024 5:11:59 PM

[External Email]

Kathy,

Thank you for your email. Please see our responses below. Liquidia will respond to UTC's July 17 letter shortly.

Best,
Robert

- **UTC's General Objections**
  - **UTC's July 23 response:** UTC's General objections are reflected in its Objections and Responses served on 6/17/2024. Your bullet below does not correctly characterize UTC's position in those objections or as stated on the call. UTC does not agree with Liquidia's position that IPF is a type of PH-ILD and the cited portions of the specification do not say so either. Without that false equivalence, Liquidia has not offered any justification for its definition of TETON or its request for any TETON-related documents. Please take another look and further try to explain the relevance of the information you're seeking regarding TETON, which includes clinical trials for different potential indications and post-dates the '327 patent.
  - **Liquidia's response:** It is unclear to us what UTC's basis is in disagreeing that IPF is a type of PH-ILD. The cited portions of the '327 patent ('327 patent at 2:53-54; 12:49-50) state that ILD "comprises" IPF and that that ILD "may include" IPF. If that were not enough, additional support can be found from hospital websites such as https://www.ucsfhealth.org/conditions/idiopathic-pulmonary-fibrosis ("UCSF offers specialized care for **all types of interstitial lung disease, including idiopathic pulmonary fibrosis**.") A quick literature search also shows that IPF is a type of ILD. *See* Sylvia M. Nikkho et al., Clinical Significance of pulmonary hypertension in interstitial lung disease: A consensus statement from the Pulmonary Vascular Research Institute's innovative drug development initiative – Group 3 pulmonary hypertension, 12 Pulmonary Circulation (2022) ("The ILDs represent a very large group of more than 200 different entities, many of which are rare or 'orphan' diseases. The idiopathic interstitial pneumonias (IIPs) are a subset of ILD of unknown etiology characterized by variable amounts of inflammation and fibrosis of the interstitial compartment. There are eight histologic subtypes of IIP, with idiopathic pulmonary fibrosis (IPF) being the most common."). The '327 patent and publicly available materials show that Liquidia's definition of "TETON trial" is relevant. Please confirm that UTC will produce documents responsive to RFP No. 36.

- **RFP #3**

- **UTC's July 23 response:** We have already agreed in response to RFP 1 to produce responsive material relating to the '327 patent. The '793 patent is not asserted, and the justification you offer below is a fishing expedition. Liquidia has also not explained how experimental data before the priority date of the '793 patent would have anything to do with "UTC's [alleged] decision to not disclose the '793 patent" over a decade later. Further, we fail to see how experimental data "may illuminate additional prior art" when Liquidia has already litigated two proceedings involving alleged invalidity of the '793 patent over the past 4+ years.
- **Liquidia's response:** The experimental work for the '793 patent is relevant because it might include PH-ILD patients. In fact, the '793 patent tables expressly disclose this. *See* '793 patent, Table 3 ("Etiology of pulmonary hypertension was classified as … pulmonary fibrosis (f)").

- **RFP #4-8**
  - **UTC's July 23 response:** On the meet and confer, you said Liquidia wanted these materials produced as some sort of concession about relevance and authenticity. Those are issues for trial, not now. Regardless, your new rationale is also flawed. In any event, is Liquidia seeking any documents beyond those that were the subject of its previous motion and the resulting modification to the PO (DI 476)? Lastly, if you request some sort of cross-use agreement, we await a draft that we can evaluate.
  - **Liquidia's response:** Liquidia will propose a draft agreement shortly.

- **RFP #9**
  - **UTC's July 23 response:** Your email asks that UTC produce documents to Liquidia because Liquidia chose to use different lawyers in the FDA case and because "UTC is already in possession of the documents responsive to this request[.]" That is also true for Liquidia, which is free to direct its own lawyers to share documents with its own lawyers consistent with governing POs. To the extent Liquidia believes it needs to re-use materials here that are governed by the protective order in that case, it should identify those materials specifically and request a modification to the appropriate PO(s).
  - **Liquidia's response:** Liquidia's request is valid and UTC's objection is not based on a rule, burden, or relevance. UTC should produce documents responsive to this request as relevant and non-burdensome. To be clear, Liquidia is looking for documents that UTC produced in the FDA action (24-484, D.D.C.), not documents that the FDA or Liquidia has produced. The protective order in the FDA action does not prevent UTC from producing its own highly-confidential information. To the extent that UTC relies on the protective order to refuse production, that is even more reason for UTC to produce those documents in this case – Liquidia's own counsel in the FDA action is prevented from disclosing UTC's highly confidential documents to Liquidia's counsel in the instant action.

- **RFP #13**
  - **UTC's July 23 response:** Please clarify whether Liquidia is looking for communications between Drs. Waxman, Tapson, and Nathan, or something else. Further, inventorship is

a legal concept and communications relating to inventorship between these individuals and UTC counsel are privileged. What types of non-privileged documents does Liquidia believe may exist that would be responsive to this RFP?

- **Liquidia's response:** Liquidia is not requesting privileged communications between the doctors and UTC counsel. Liquidia is requesting non-privileged communications involving Drs. Aaron Waxman, Victor Tapson, or Steven D. Nathan showing their contributions to the conception of the subject matter claimed in the '327 patent. Those communications would be between those three individuals, collectively or separately, and UTC.

- **RFP #16-17**
  - **UTC's July 23 response:**
    - For RFP 16, please clarify what if anything you seek beyond what we have agreed to provide in response to RFP 1.
    - For RFP 17, publications by the named inventors would be publicly available to Liquidia. Please clarify what Liquidia is seeking beyond what it can find for itself.
  - **Liquidia's response:** Liquidia has already stated that it is "amenable to limit this request to communications and publications regarding PH-ILD and the treatment of PH-ILD with inhaled treprostinil." More specifically, we are requesting communications and publications involving Leigh Peterson, Peter Smith, and Chunqin Deng regarding PH-ILD and the treatment of PH-ILD with inhaled treprostinil. Liquidia's requests encompass communications and draft publications which would not be publicly available to Liquidia. To the extent that UTC argues that RFP No. 16 is encompassed by what UTC has agreed to produce in response to RFP No. 1, please confirm that such production will include communications and draft publications involving Leigh Peterson, Peter Smith, and Chunqin Deng regarding PH-ILD and the treatment of PH-ILD with inhaled treprostinil.

- **RFP #18**
  - **UTC's July 23 response:** For RFP 18, Liquidia has already conducted a search for studies before the priority date of the '327 patent, and indeed has cited studies it thinks are relevant in its invalidity contentions. Liquidia is also free to search the public domain for posters. The quoted statement, moreover, neither cites any particular presentations, papers, or posters, nor indicates Dr. Rothblatt recalls data or information that cover the breadth of Liquidia's RFP. Please explain why UTC should search publicly available material that Liquidia has already searched for.
  - **Liquidia's response:** The scope and breadth of Liquidia's prior art searches should have no bearing on the scope of UTC's own discovery obligations. There is also no indication that Dr. Rothblatt **does not** recall the information in the FQ1 2018 Earnings Call Transcript. UTC can easily obtain and produce this information by asking Dr. Rothblatt, reviewing her communications, including emails, and internal communications leading up to Dr. Rothblatt's decision to make this statement.

- **RFP #56**
  - **UTC's July 23 response:** For RFP 56, please let us know why the full scope—"All

documents and things related to" the stated subject—is relevant and proportional to the needs of the case, including which claim or defense is implicated.

- **Liquidia's response:** Liquidia has already indicated in its July 8 email that RFP #56 is at least relevant to the determination of any alleged damages or alleged irreparable harm that UTC may suffer from Liquidia's launch of Yutrepia. UTC's First Amended Complaint seeks a permanent injunction as well as damages. Documents responsive to this RFP are relevant to Liquidia's defense against both of those prayers for relief. This is also information that UTC can easily obtain and produce by asking Dr. Rothblatt and reviewing her communications, including emails.

- **RFP #19**
  - **UTC's July 23 response:** This request is vague, not relevant, overly broad and unduly burdensome, and not proportional to the needs of the case. And Liquidia's proposed narrowing makes the request more vague. As served, RFP 19 sought a broad category of documents, including communications "with UTC and the named inventors of the '327 patent . . . ." Now, Liquidia's proposed narrower version seeks communications with the named inventors "of the '200 publication." Please also explain why either (1) an abandoned publication with different inventors than the claims-at-issue or (2) "the subject matter of Examples 4-6 and related Figures of the '200 publication" are relevant and proportional to the needs of this case. Further, please clarify what is meant by "related Figures," as the publication has none.
  - **Liquidia's response:** Liquidia disagrees with UTC's objections. Abandoned patent applications can still be prior art if they have been publicly disclosed through publication. *See Lee Pharmaceutical v. Kreps,* 577 F.2d 610, 613 (9th Cir. 1978). The '200 publication reflects UTC's own patent application for the use of inhaled treprostinil for the treatment of PH-ILD. Communications with the named inventors of the '200 publication would, at least, be relevant to UTC's knowledge of the '200 publication and its subject matter, and thus be relevant to the enforceability of the '327 patent.

- **RFP #20**
  - **UTC's July 23 response:** Please clarify why Liquidia needs these documents from UTC. UTC does not intend to withhold public documents that it locates in its searches for, e.g., RFP 1, merely because they are public. But please confirm and if possible justify why, under the relevant circumstances, Liquidia contends that UTC should go and collect public documentation equally accessible to Liquidia that Liquidia wishes to rely on for its defenses.
  - **Liquidia's response:** Liquidia has already explained why RFP 20 is relevant in its previous July 8 email. Neither UTC's objections to Liquidia's 1st Set of RFPs nor UTC's July 23 email objects to the relevance of this RFP. And despite UTC's email response saying that "UTC does not intend to withhold public documents that it locates in its searches … merely because they are public," it seems as if UTC is doing just that. The District of Delaware has sustained document production requests and granted motions to compel over objections that the requested documents are publicly available. *See EON Corp. IP Holdings, LLC v. FLO TV Inc.*, 2013 WL 5882005, at *1-4 (D. Del. July 18,

2013).

- **RFPs #21-31**
  - **UTC's July 23 response:** RFPs 21-26, 28, and 30 relate to communications with certain individuals. RFPs 27, 29, and 31 relate to decisions whether to fund certain studies. UTC disputes that these requests are relevant and proportional to the needs of the case, but UTC is investigating these RFPs and will respond further in due course. In the meantime, please explain why the full scope of Liquidia's requests is allegedly relevant and proportional to the needs of the case when there are other, less burdensome ways to discover "physicians' practices in treating PH-ILD with inhaled treprostinil."
  - **Liquidia's response:** Liquidia has already explained why RFPs 21-31 are relevant in its previous July 8 email. It is also unclear to Liquidia what "other, less burdensome ways" to obtain discovery that UTC is referring to. To the extent that UTC is suggesting that Liquidia search for publicly available materials such as publications and posters, that does not reveal UTC's knowledge of physicians' practices treating PH-ILD with treprostinil. To spell things out, such knowledge is relevant to the unenforceability of the '327 patent.

- **RFPs #32-35**
  - **UTC's July 23 response:**
    - For RFPs 32-33, please let us know what you are looking for beyond what UTC has agreed to provide in response to RFP 1.
    - RFP 34 seeks "communications with, and statements made to, the general public and investors . . . ." Please confirm and if possible justify why, under the relevant circumstances, Liquidia contends that UTC should go and collect public documentation equally accessible to Liquidia that Liquidia wishes to rely on for its defenses.
    - RFP 35 is vague, at least as to "the documentation relied on to support the INCREASE study." Further, the request otherwise appears directed to information post-dating the '327 patent. Please explain the relevance and proportionality of this request so that we can consider whether and what information may possibly be discoverable.
  - **Liquidia's response:**
    - RFP No. 32 does not completely overlap with RFP No. 1. The scope of RFP No. 32 includes posters, abstracts, presentations, protocols, steering committee minutes related to the INCREASE study that is not necessarily captured by RFP No. 1. To the extent that UTC argues that its production for RFP No. 1 is sufficient to address RFP No. 32, please confirm that the production for RFP No. 1 includes posters, abstracts, presentations, protocols, steering committee minutes related to the INCREASE study.
    - Liquidia thinks that RFP No. 33 will be adequately addressed by the production in RFP No. 1.
    - Regarding RFP No. 34, UTC does not argue against the relevance of this request in its July 23 email. Statements that UTC made to its investors are not necessarily publicly available. And in any event, as explained above for RFP No.

20, the mere fact that requested documents and communications are publicly available does not shield UTC from its discovery obligations.

- Liquidia does not agree that RFP No. 35 is vague. To be clear, RFP No. 35 seeks documentation used to support or justify any retrospective or post-hoc studies evaluating forced vital capacity in patients being treated with inhaled treprostinil from the INCREASE study. RFP No. 35 is relevant to the inventorship and enablement of the '327 patent's dependent claims regarding forced vital capacity.

- **RFP #36**
  - **UTC's July 23 response:** First, we direct you to the discussion of UTC's General Objections above. Further, this RFP appears directed solely to material that post-dates the INCREASE trial and '327 patent. You state that the request is "relevant to the validity of the '327 patent claims directed at FVC and exacerbations." Please explain why this post-priority information is allegedly relevant to validity of the '327 patent.
  - **Liquidia's response:** We explain the relevance of the TETON trial in our response to UTC's general objections above. RFP No. 36 is relevant to issues of enablement for the dependent claims regarding forced vital capacity exacerbations and informs the prior art, for example, on what treprositnil is improving for FVC. That the information might post-date the '327 patent is not a basis to withhold such information and, nonetheless, still informs on the issue of validity of the '327 patent.

- **RFP #37**
  - **UTC's July 23 response:** Can you clarify what you mean by the assertion that these requested documents "inform at least the prior art and potential prior art"? In addition, this RFP seeks "all documents and things concerning" six categories of technical and scientific subject matter: not exactly a "narrow set of documents." But if you have a narrow category or specific documents in mind, please identify them so that we can assess whether UTC has those documents and whether UTC has objections to their production.
  - **Liquidia's response:** "Informs … the prior art" means that the requested documents would provide information regarding the scope and meaning of the prior art.

- **RFPs #38-39, 46**
  - **UTC's July 23 response:** These Requests are overly broad, seek irrelevant documents, are vague and ambiguous, not proportional, and include privileged patient information. For example, RFP 38 by its terms seeks communications between "UTC and … patients," as does RFP 46 ("potential patients, or patients"). RFP 46 appears redundant to RFPs 38-39, and additionally vague for seeking communications with "potential customers, customers, … potential patients," and it also is unbounded as to time, thus apparently including any communications after UTC received FDA approval for Tyvaso and/or Tyvaso DPI for the treatment of PH-ILD. We think it would be helpful if you could consider whether RFP 46 seeks anything beyond RFPs 38-39 and if 38-39 can be narrowed. We further note that it is unclear what Liquidia seeks with these RFPs beyond the documents sought by RFPs 21-31. And we further request Liquidia identify

what specific "public statements by Dr. Rothblatt in 2018" demonstrate "physicians . . . were communicating with UTC about" using Tyvaso for PH-ILD.

- **Liquidia's response:** Liquidia seeks documents responsive to these RFPs that do not include privileged patient information. Information sought by RFP #38-39 that is not captured by RFP #21-31 would include, as non-limiting examples, patient consent forms and patient brochures regarding the administration of Tyvaso for PH-ILD. "[P]ublic statements by Dr. Rothblatt in 2018" refers to public statements by Dr. Rothblatt in UTC's FQ1 2018 Earnings Call, dated May 2, 2018. *See* D.I. 52, Ex. 1 at LIQ_PH-ILD_00000010. As a specific example, Dr. Rothblatt stated that "Having said that, both through the effort of our medical affairs group over the years in supporting investigator-sponsored studies and through the kindness and generosity of certain payers around the country who have gone ahead and upon the initiative of their physicians, were able to enable some WHO Group III patients to benefit, there were unmistakable signals the some of the leading physicians in this field." Liquidia has delineated RFPs #38-39, 46 to make clear what Liquidia is seeking from UTC. To the extent that UTC believes what is sought in RFP No. 46 is encompassed by RFP Nos. 38 and/or 39, then please state so and produce responsive documents under RFP Nos. 38 and/or 39.

- **RFPs #40-42**
  - **UTC's July 23 response:**
    - Please confirm what "non-overlapping" documents Liquidia seeks through these RFPs beyond the subject matter UTC has agreed to produce in response to RFP 1 and any alleged relevance to information that post-dates the '327 patent.
    - For RFP No. 42, Liquidia's request for key opinion leader documents back to 2009 departs from the District of Delaware's default rules that limit discovery of ESI to 6 years. Please explain why such discovery is allegedly justified back to 2009.
  - **Liquidia's response:**
    - These RFPs are broader than RFP No. 1 because these RFPs seek information on treprostinil and PH-ILD, and are not limited to just inhaled treprostinil.
    - UTC's own patent applications, such as US 2013/0096200, which Liquidia relies on as prior art, pre-date Sept. 5, 2017 (the ESI limit of 6 years per the default rules). UTC itself has submitted patent applications directed to highly relevant subject matter that pre-date the 6-year ESI limit.

- **RFP #43-44**
  - **UTC's July 23 response:** UTC is willing to consider production of these NDAs, but we await your response to our July 16 letter regarding UTC RFPs 1-3 and the definitions implicated by those RFPs.
  - **Liquidia's response:** Liquidia will respond to UTC's letter shortly.

- **RFP #45**
  - **UTC's July 23 response:** Please explain how UTC's device samples are relevant to claim construction of pulsed inhalation device and what they have to do with "the validity of

the '327 patent."

- **Liquidia's response:** UTC's device samples would inform claim construction regarding terms such as "pulsed inhalation device." It would also inform Liquidia's enablement argument regarding the '327 patent limitation in dependent claim 14, "Pulsed Inhalation Device is a Dry Powder Inhaler." UTC has also requested samples of Liquidia's "Commercial Drug Product Kits" in UTC's RFP No. 25, and Liquidia plans to produce materials responsive to that request.

- **RFP #47-57, 61-63**
  - **UTC's July 23 response:**
    - Liquidia has all but refused any financial production in response to UTC's RFPs, and has implied if not threatened to improperly redact documents it does produce. Further, Liquidia postured during the meet and confer and in response to UTC RFP Nos. 4 and 9, that documents related to Liquidia's launch of Yutrepia for PH-ILD and related financial production become relevant "if and when Liquidia launches Yutrepia™ for PH-ILD". Similarly, in response to UTC RFP No. 11, Liquidia outright declined to produce any documents, and in response to UTC RFP No. 13, Liquidia seemingly declined to produce forecasted and potential financial documents. Yet Liquidia seeks incredibly broad categories of financial discovery from UTC, without any conditional limitation as to their relevance and proportionality, justified only by the assertion that the documents are "highly" relevant to damages and irreparable harm. That these requests are "limited to PH-ILD and Tyvaso®" and Yutrepia does not necessarily make them "narrow in scope." In reality, Liquidia's requests are quite broad. For example, RFPs 47-57 and 61 all demand "[a]ll" responsive documents. RFP 48 demands "*All* UTC internal communications regarding *potential or actual competition from any Liquidia treprostinil product*, including Yutrepia." Please explain why Liquidia contends these are narrow and allegedly proportional Requests. UTC is willing to consider a proportional production of relevant, non-privileged financial documents located after a reasonable search, if any, but we await your response to our July 16 letter regarding UTC RFPs 4, 9, 11 and 13 and the definitions implicated by those RFPs.
  - **Liquidia's response:** There is no scenario in which Liquidia's forecasted and projected financial documents are relevant in this case. Liquidia's financial documents are irrelevant prior to Liquidia's launch of Yutrepia, as UTC would not have incurred any damages prior to Liquidia's launch. Once Liquidia launches Yutrepia, Liquidia will produce financial documents reflecting actual sales, revenue, pricing, etc. On the other hand, Liquidia's requests are relevant because Tyvaso and Tyvaso DPI have already launched. To the extent that UTC argues that Liquidia's RFPs #47-57, 61 are overbroad because they ask for "[a]ll documents and things," Liquidia is willing to limit the scope of certain requests as follows in the spirit of compromise. Liquidia will respond to UTC's July 17 letter regarding UTC RFPs 4, 9, 11, and 13.
    - RFP #50: "~~All~~ documents and things sufficient to show ~~related to~~ the market size of pulmonary arterial hypertension."
    - RFP #51: "~~All~~ documents and things sufficient to show ~~related to~~ the market size

of pulmonary hypertension associated with interstitial lung disease."

- RFP #52: "~~All~~ documents and things sufficient to show ~~related to~~ UTC's pre-2023 pricing strategy for TYVASO® and TYVASO DPI® used for the treatment of 'pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability.'"
- RFP #53: "~~All~~ documents and things sufficient to show ~~related to~~ UTC's post-2023 pricing strategy for TYVASO® and TYVASO DPI® used for the treatment of 'pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability.'"
- RFP #54: "~~All~~ documents and things sufficient to show ~~related to~~ UTC's pre-2023 pricing strategy for TYVASO® and TYVASO DPI® used for the treatment of 'pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.'"
- RFP #55: "~~All~~ documents and things sufficient to show ~~related to~~ UTC's post-2023 pricing strategy for TYVASO® and TYVASO DPI® used for the treatment of 'pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.'"
- RFP #56: "~~Al~~ documents and things ~~related to~~ sufficient to show the basis for Martine A. Rothblatt's statement that UTC is 'confident in [their] ability to double [their] annual revenue run rate for approximately $2 billion to $4 billion by the end of 2025[,]' in the Q4 2022 UTC Earnings call (LIQ_PH-IL D_00000013)."
- RFP #57: "~~Al~~ documents and things ~~related to~~ sufficient to show the bases underlying UTC's TYVASO® Forecast for 2023-2035 (UTC_PH-ILD_009410) including documents and things related to the breakdown of the U.S. Market by the TYVASO® indications, the number of TYVASO® Treated Patients broken down by TYVASO® indication, and the U.S. Net Revenue broken down by TYVASO® indication."
- RFP #61: "~~All~~ documents and things ~~concerning~~ sufficient to show the contractual terms on which Plaintiff has sold, or will sell in the future, TYVASO®, TYVASO DPI®, or any other treprostinil products, to any third party."

- **RFP #66**
  - **UTC's July 23 response:** Please identify what, if any, allegedly non-privileged documents are sought by this RFP.
  - **Liquidia's response:** This RFP is related to Liquidia's inequitable conduct theory. Liquidia is entitled to know if such non-privileged documents exist. If unwilling to review and produce, or log in a privilege log, then UTC should so state and Liquidia will, at the appropriate time, seek to obtain the relevant adverse inferences]

- **RFP #68**
  - **UTC's July 23 response:** RFP 68 is overly broad, not relevant, unduly burdensome, and not proportional. Liquidia's email merely states in conclusory fashion that the subject matter is relevant to the pulsed inhalation device claims at issue and damages. Please explain how R&D for the Dreamboat device relates to Liquidia's infringement of those

claims.

- **Liquidia's response:** Documents related to the R&D of Mannkind Corporation's Dreamboat device are directly relevant to the "pulsed inhalation device" claims. How the Dreamboat device is described (either as a pulsed inhalation device or not) in the documents and communications regarding the device will be probative as to the scope of the term "pulsed inhalation device."

- **RFP #69**
  - **UTC's July 23 response:** RFP 69 is overly broad, not relevant, unduly burdensome, and not proportional. It seeks, for example, all agreements used in development or "implicated" by the sale of Tyvaso DPI®, which is also vague and unclear. Please explain why Liquidia believes it is entitled to the full scope of this RFP or propose a narrower request.
  - **Liquidia's response:** Liquidia is willing to limit this request to "All licenses or agreements ~~necessary to,~~ used in ~~the development of, or implicated by~~ the sale of TYVASO DPI®."

- **RFP #70**
  - **UTC's July 23 response:** RFP 70 suffers from similar flaws as RFP 68 and 69.
  - **Liquidia's response:** Liquidia is willing to limit this request to "All licenses or agreements ~~necessary to,~~ used in ~~the development of, or implicated by~~ the sale of the Dreamboat® inhalation device."

- **RFP #71**
  - **UTC's July 23 response:** Please explain what non-privileged documents you seek that would be responsive to RFP 71.
  - **Liquidia's response:** It is unclear to Liquidia how RFP #71 would implicate privileged information. It is UTC, not Liquidia, that is in possession of "[d]ocuments sufficient to describe UTC's policies, practices, or procedures with respect to patent licensing," and Liquidia would not know the types of non-privileged documents that are responsive to this request. To be clear, Liquidia is not seeking privileged information in response to this request. Indeed, UTC's policies should not be privileged as they are shared within the company. And Liquidia is not seeking drafts of those policies.

- **RFP #72**
  - **UTC's July 23 response:** RFP 72 is overly broad, not relevant, unduly burdensome, and not proportional. It seeks, for example, "All" documents, including "potential" licenses, and "drafts" of "potential licenses, related to the asserted '327 patent, and a presently unasserted '793 patent, and unidentified "Related Patents and Applications." Please explain why Liquidia believes it is entitled to the full scope of this RFP or propose a narrower request.
  - **Liquidia's response:** Liquidia is willing to limit this request to "All licenses~~, potential licenses, and drafts thereof,~~ of intellectual property rights relating to ~~the '793 patent,~~ the '327 patent, and/or related patents and applications."

RFP #73

- **UTC's July 23 response:** RFPs 73-75 suffers from similar flaws as RFP 72.
- **Liquidia's response:** Liquidia is willing to limit this request to "~~All~~ documents sufficient to show ~~constituting or relating to~~ UTC's valuation or projection of license fees or potential license fees related to ~~the '793 patent,~~ the '327 Patent, and/or Related Patents and Applications."

- **RFP #74**
  - **Liquidia's response:** Liquidia is willing to limit this request to "Documents concerning any technology or patent license~~, or settlement,~~ offered to or by, or accepted by UTC, relating to treprostinil, including an accounting of royalties or licensing fees paid."

- **RFP #75**
  - **Liquidia's response:** Liquidia is willing to limit this request to "Documents concerning any technology or patent license~~, or settlement,~~ offered to or by, or accepted by UTC, relating to TYVASO®, TYVASO DPI®, or any other treprostinil products, including an accounting of royalties or licensing fees paid."

From: Pappas, Katherine <Kpappas@mwe.com>
Sent: Tuesday, July 23, 2024 11:31 AM
To: Minn, Robert <rminn@cooley.com>; Dykhuis, Art <Adykhuis@mwe.com>; jblumenfeld@morrisnichols.com; mflynn@morrisnichols.com; Carsten, Douglas <Dcarsten@mwe.com>; Burrowbridge, Adam <Aburrowbridge@mwe.com>; Cheng, Katherine <KatherineCheng@goodwinlaw.com>; Rosner, Gail D <grosner@goodwinlaw.com>
Cc: z/Liquidia v UTC 308970-201 <zLiquidiavUTC308970201@cooley.com>; Karen Keller <kkeller@shawkeller.com>; nhoeschen@shawkeller.com; Emily DiBenedetto <edibenedetto@shawkeller.com>; DG-ILD <DG-ILD@goodwinlaw.com>; UTCvLiquidia-Del-23cv975 <UTCvLiquidia-Del-23cv975@mwe.com>
Subject: RE: UTC v. Liquidia (23-975) - RFP M&C Follow-up

[External]

Robert,

Thanks for your email. We respond to the items you raised below.

- UTC's General Objections
  - UTC's General objections are reflected in its Objections and Responses served on 6/17/2024. Your bullet below does not correctly characterize UTC's position in those objections or as stated on the call. UTC does not agree with Liquidia's position that IPF is a type of PH-ILD and the cited portions of the specification do not say so either. Without that false equivalence, Liquidia has not offered any justification for its definition of TETON or its request for any TETON-related documents. Please take another look and further try to explain the relevance of the information you're seeking

regarding TETON, which includes clinical trials for different potential indications and post-dates the '327 patent.

- RFP 3
  - We have already agreed in response to RFP 1 to produce responsive material relating to the '327 patent. The '793 patent is not asserted, and the justification you offer below is a fishing expedition. Liquidia has also not explained how experimental data before the priority date of the '793 patent would have anything to do with "UTC's [alleged] decision to not disclose the '793 patent" over a decade later. Further, we fail to see how experimental data "may illuminate additional prior art" when Liquidia has already litigated two proceedings involving alleged invalidity of the '793 patent over the past 4+ years.
- RFPs 4-8
  - On the meet and confer, you said Liquidia wanted these materials produced as some sort of concession about relevance and authenticity. Those are issues for trial, not now. Regardless, your new rationale is also flawed. In any event, is Liquidia seeking any documents beyond those that were the subject of its previous motion and the resulting modification to the PO (DI 476)? Lastly, if you request some sort of cross-use agreement, we await a draft that we can evaluate.
- RFP 9
  - Your email asks that UTC produce documents to Liquidia because Liquidia chose to use different lawyers in the FDA case and because "UTC is already in possession of the documents responsive to this request[.]" That is also true for Liquidia, which is free to direct its own lawyers to share documents with its own lawyers consistent with governing POs. To the extent Liquidia believes it needs to re-use materials here that are governed by the protective order in that case, it should identify those materials specifically and request a modification to the appropriate PO(s).
- RFPs 10-11
  - Our recollection of the meet and confer differs. But to the extent you narrow these RFPs to non-privileged information, there would be no need for a privilege log as no privileged information would be responsive. With that narrowed scope, the dispute is moot, as we are also not aware of non-privileged documents that are responsive to these RFPs.
- RFP 13
  - Please clarify whether Liquidia is looking for communications between Drs. Waxman, Tapson, and Nathan, or something else. Further, inventorship is a legal concept and communications relating to inventorship between these individuals and UTC counsel are privileged. What types of non-privileged documents does Liquidia believe may exist that would be responsive to this RFP?
- RFPs 16-17
  - For RFP 16, please clarify what if anything you seek beyond what we have agreed to provide in response to RFP 1.
  - For RFP 17, publications by the named inventors would be publicly available to Liquidia. Please clarify what Liquidia is seeking beyond what it can find for itself.
- RFPs 18, 56
  - For RFP 18, Liquidia has already conducted a search for studies before the priority date

of the '327 patent, and indeed has cited studies it thinks are relevant in its invalidity contentions. Liquidia is also free to search the public domain for posters. The quoted statement, moreover, neither cites any particular presentations, papers, or posters, nor indicates Dr. Rothblatt recalls data or information that cover the breadth of Liquidia's RFP. Please explain why UTC should search publicly available material that Liquidia has already searched for.

- For RFP 56, please let us know why the full scope—"All documents and things related to" the stated subject—is relevant and proportional to the needs of the case, including which claim or defense is implicated.

- RFP 19
  - This request is vague, not relevant, overly broad and unduly burdensome, and not proportional to the needs of the case. And Liquidia's proposed narrowing makes the request more vague. As served, RFP 19 sought a broad category of documents, including communications "with UTC and the named inventors of the '327 patent . . . ." Now, Liquidia's proposed narrower version seeks communications with the named inventors "of the '200 publication." Please also explain why either (1) an abandoned publication with different inventors than the claims-at-issue or (2) "the subject matter of Examples 4-6 and related Figures of the '200 publication" are relevant and proportional to the needs of this case. Further, please clarify what is meant by "related Figures," as the publication has none.
- RFP 20
  - Please clarify why Liquidia needs these documents from UTC. UTC does not intend to withhold public documents that it locates in its searches for, e.g., RFP 1, merely because they are public. But please confirm and if possible justify why, under the relevant circumstances, Liquidia contends that UTC should go and collect public documentation equally accessible to Liquidia that Liquidia wishes to rely on for its defenses.
- RFPs 21-31
  - RFPs 21-26, 28, and 30 relate to communications with certain individuals. RFPs 27, 29, and 31 relate to decisions whether to fund certain studies. UTC disputes that these requests are relevant and proportional to the needs of the case, but UTC is investigating these RFPs and will respond further in due course. In the meantime, please explain why the full scope of Liquidia's requests is allegedly relevant and proportional to the needs of the case when there are other, less burdensome ways to discover "physicians' practices in treating PH-ILD with inhaled treprostinil."
- RFPs 32-35
  - For RFPs 32-33, please let us know what you are looking for beyond what UTC has agreed to provide in response to RFP 1.
  - RFP 34 seeks "communications with, and statements made to, the general public and investors . . . ." Please confirm and if possible justify why, under the relevant circumstances, Liquidia contends that UTC should go and collect public documentation equally accessible to Liquidia that Liquidia wishes to rely on for its defenses.
  - RFP 35 is vague, at least as to "the documentation relied on to support the INCREASE study." Further, the request otherwise appears directed to information post-dating the '327 patent. Please explain the relevance and proportionality of this request so that we

can consider whether and what information may possibly be discoverable.

- RFP 36
  - First, we direct you to the discussion of UTC's General Objections above. Further, this RFP appears directed solely to material that post-dates the INCREASE trial and '327 patent. You state that the request is "relevant to the validity of the '327 patent claims directed at FVC and exacerbations." Please explain why this post-priority information is allegedly relevant to validity of the '327 patent.
- RFP 37
  - Can you clarify what you mean by the assertion that these requested documents "inform at least the prior art and potential prior art"? In addition, this RFP seeks "all documents and things concerning" six categories of technical and scientific subject matter: not exactly a "narrow set of documents." But if you have a narrow category or specific documents in mind, please identify them so that we can assess whether UTC has those documents and whether UTC has objections to their production.
- RFPs 38-39, 46
  - These Requests are overly broad, seek irrelevant documents, are vague and ambiguous, not proportional, and include privileged patient information. For example, RFP 38 by its terms seeks communications between "UTC and … patients," as does RFP 46 ("potential patients, or patients"). RFP 46 appears redundant to RFPs 38-39, and additionally vague for seeking communications with "potential customers, customers, … potential patients," and it also is unbounded as to time, thus apparently including any communications after UTC received FDA approval for Tyvaso and/or Tyvaso DPI for the treatment of PH-ILD. We think it would be helpful if you could consider whether RFP 46 seeks anything beyond RFPs 38-39 and if 38-39 can be narrowed. We further note that it is unclear what Liquidia seeks with these RFPs beyond the documents sought by RFPs 21-31. And we further request Liquidia identify what specific "public statements by Dr. Rothblatt in 2018" demonstrate "physicians . . . were communicating with UTC about" using Tyvaso for PH-ILD.
- RFPs 40-42
  - Please confirm what "non-overlapping" documents Liquidia seeks through these RFPs beyond the subject matter UTC has agreed to produce in response to RFP 1 and any alleged relevance to information that post-dates the '327 patent.
  - For RFP No. 42, Liquidia's request for key opinion leader documents back to 2009 departs from the District of Delaware's default rules that limit discovery of ESI to 6 years. Please explain why such discovery is allegedly justified back to 2009.
- RFPs 43-44
  - UTC is willing to consider production of these NDAs, but we await your response to our July 16 letter regarding UTC RFPs 1-3 and the definitions implicated by those RFPs.
- RFP 45
  - Please explain how UTC's device samples are relevant to claim construction of pulsed inhalation device and what they have to do with "the validity of the '327 patent."
- RFPs 47-57, 61-63
  - Liquidia has all but refused any financial production in response to UTC's RFPs, and has implied if not threatened to improperly redact documents it does produce. Further, Liquidia postured during the meet and confer and in response to UTC RFP Nos. 4 and 9,

that documents related to Liquidia's launch of Yutrepia for PH-ILD and related financial production become relevant "if and when Liquidia launches Yutrepia™ for PH-ILD". Similarly, in response to UTC RFP No. 11, Liquidia outright declined to produce any documents, and in response to UTC RFP No. 13, Liquidia seemingly declined to produce forecasted and potential financial documents. Yet Liquidia seeks incredibly broad categories of financial discovery from UTC, without any conditional limitation as to their relevance and proportionality, justified only by the assertion that the documents are "highly" relevant to damages and irreparable harm. That these requests are "limited to PH-ILD and Tyvaso®" and Yutrepia does not necessarily make them "narrow in scope." In reality, Liquidia's requests are quite broad. For example, RFPs 47-57 and 61 all demand "[a]ll" responsive documents. RFP 48 demands "*All* UTC internal communications regarding *potential or actual competition from any Liquidia treprostinil product*, including Yutrepia." Please explain why Liquidia contends these are narrow and allegedly proportional Requests. UTC is willing to consider a proportional production of relevant, non-privileged financial documents located after a reasonable search, if any, but we await your response to our July 16 letter regarding UTC RFPs 4, 9, 11 and 13 and the definitions implicated by those RFPs.

- RFP 66
  - Please identify what, if any, allegedly non-privileged documents are sought by this RFP.
- RFP 67
  - As stated, UTC will produce responsive non-privileged non-public documents specifically cited in UTC's responses to Liquidia's interrogatories, to the extent that such documents exist and are found in its possession, custody, or control after a reasonably diligent search of its files. UTC agrees not to withhold documents cited in its responses on the basis that they are unrelated to the '327 patent. Of course, if UTC cites documents that Liquidia or another entity has already produced, it will not re-produce those. UTC also will not produce documents "considered" during preparation of its interrogatory responses.
- RFPs 68-75
  - RFP 68 is overly broad, not relevant, unduly burdensome, and not proportional. Liquidia's email merely states in conclusory fashion that the subject matter is relevant to the pulsed inhalation device claims at issue and damages. Please explain how R&D for the Dreamboat device relates to Liquidia's infringement of those claims.
  - RFP 69 is overly broad, not relevant, unduly burdensome, and not proportional. It seeks, for example, all agreements used in development or "implicated" by the sale of Tyvaso DPI®, which is also vague and unclear. Please explain why Liquidia believes it is entitled to the full scope of this RFP or propose a narrower request.
  - RFP 70 suffers from similar flaws as RFP 68 and 69.
  - Please explain what non-privileged documents you seek that would be responsive to RFP 71.
  - RFP 72 is overly broad, not relevant, unduly burdensome, and not proportional. It seeks, for example, "All" documents, including "potential" licenses, and "drafts" of "potential licenses, related to the asserted '327 patent, and a presently unasserted '793 patent, and unidentified "Related Patents and Applications." Please explain why Liquidia believes it is entitled to the full scope of this RFP or propose a narrower

request.
- RFPs 73-75 suffers from similar flaws as RFP 72.

We look forward to your responses.

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Cc: z/Liquidia v UTC 308970-201 <zLiquidiavUTC308970201@cooley.com>; Karen Keller <kkeller@shawkeller.com>; nhoeschen@shawkeller.com; Emily DiBenedetto <edibenedetto@shawkeller.com>; DG-ILD <DG-ILD@goodwinlaw.com>; UTCvLiquidia-Del-23cv975 <UTCvLiquidia-Del-23cv975@mwe.com>
Subject: UTC v. Liquidia (23-975) - RFP M&C Follow-up

[External Email]
Counsel,

Please see below Liquidia's positions regarding Liquidia's RFPs to which UTC has refused to produce documents or sought a meet-and-confer. Please let us know your response and whether the parties can resolve these issues down to a more manageable number of RFPs before a second meet-and-confer.
Thank you.

Robert

- UTC's General Objections
  - UTC argued that the definition of "TETON trial" was overbroad and irrelevant because idiopathic pulmonary fibrosis was not relevant to PH-ILD.
  - Liquidia's position: Idiopathic pulmonary fibrosis (IPF) is disclosed in the '327 patent as a type of PH-ILD. It is Liquidia's position that the definition of TETON trial is proportional and relevant.
    - "In some embodiments, the ILD comprises one or more of idiopathic pulmonary fibrosis (IPF)." '327 patent at 2:53-54.
    - "ILD may include a range of diseases and disorders, for example, idiopathic pulmonary fibrosis (IPF)." '327 patent at 12:49-50.
- UTC's Specific Objections

- **RFP No. 3**
  - Liquidia's position: These documents are relevant because they relate to Liquidia's invalidity and inequitable conduct defenses concerning the '793 patent. Specifically, the experimental data may illuminate additional prior art or UTC's decision to not disclose the '793 patent in the prosecution of the '327 patent.
- **RFP Nos. 4-8**
  - These RFPs concern materials and documents related to the '793 patent from previous litigations. UTC refused to produce because Liquidia already has copies and as irrelevant because they relate to a separate case.
  - Liquidia's position: It is unclear from the language of the Modification to the Protective Order (D.I. 476) in the 20-755 Delaware case whether the Court has extended the protective order in that case to just the preliminary injunction briefing or the entire 23-975 case. Liquidia is amenable to narrowing this request to documents concerning the conception and reduction to practice of the invention claimed by the '793 patent. Liquidia is also amenable to a cross-use agreement that would allow the parties to rely on documents in the 20-755 Delaware case.
- **RFP No. 9**
  - UTC refused to produce on the basis that (1) because Liquidia is intervening in the 24-484 FDA action, it already has access to these documents and (2) the protective order in the 24-484 FDA case prevented them from reproducing documents in this litigation.
  - Liquidia's position: Liquidia notes that the PO in the 24-484 FDA action (D.I. 27 at 3) places restrictions on the production of Highly Confidential Information. Liquidia is amenable to narrowing this RFP to non-Highly Confidential Information. Counsel for Liquidia in the current D. Del. action does not represent Liquidia in the 24-484 FDA action, whereas the attorneys of record for UTC are in both the 23-975 Delaware action as well as the 24-484 FDA action. UTC is already in possession of the documents responsive to this request and it would not be burdensome for UTC to produce the documents.
- **RFP Nos. 10-11**
  - UTC objected to these RFPs, which concern UTC's decision to not disclose the '793 patent during prosecution of the '327 patent and UTC's decision to initially assert the '793 patent in this case, on the basis that they include privileged information.
  - Liquidia's position: Liquidia requests that UTC produce any non-privileged information identified after a reasonable search. UTC indicated that it would be amenable to providing a privilege log if Liquidia limits these RFPs to non-privileged information.
- **RFP No. 13**
  - This RFP asks for all communications with Drs. Waxman, Tapson, and Nathan regarding the inventorship of the '327 patent.
  - Liquidia's position: By UTC's own admission, the '327 patent describes the INCREASE trial (*see* D.I. 26 at 11), and UTC has alleged that the results of this trial

demonstrate the non-obviousness of its '327 patent (*see id.* at 13.) Drs. Waxman, Tapson, and Nathan served on the steering committee for the INCREASE study, and thus communications regarding inventorship with these three will speak to inventorship of the '327 patent.

- **RFP Nos. 16-17**
  - Liquidia's position: The named inventor's communications and publications regarding the subject matter of the '327 patent are directly relevant to the validity and enforceability of the '327 patent. Liquidia is amenable to limit this request to communications and publications regarding PH-ILD and the treatment of PH-ILD with inhaled treprostinil.
- **RFP Nos. 18, 56**
  - Liquidia's position: These requests are narrow and not burdensome in that they seek the limited set of documents that Dr. Rothblatt had observed. RFP No. 18 is relevant to the invalidity of the '327 patent in that it references, in 2018, posters on treating PH-ILD with inhaled treprostinil. RFP No. 56 is relevant to UTC's allegations of irreparable harm and damages.
- **RFP No. 19**
  - Liquidia's position: This request is relevant because it seeks documents and things concerning the subject matter of the '200 publication, a prior art UTC publication to the '327 patent. In the interest of compromise, Liquidia is willing to limit this request to documents and things, including communications with the named inventors of the '200 publication, concerning the subject matter of Examples 4-6 and related Figures of the '200 publication.
- **RFP No. 20**
  - Liquidia's position: This request seeks presentations, papers, and posters on the use of treprostinil in PH-ILD studies that UTC has sponsored, and is thus directly relevant to identification of prior art and invalidity in this matter. The request seeks only those presentations, papers, and posters sponsored by UTC concerning use of treprostinil in PH-ILD, and is thus both narrow in scope and limited to documents likely to be in UTC's possession, custody, or control.
- **RFP Nos. 21-31**
  - Liquidia's position: These requests seek communications between UTC and physicians, some of which who were authors of prior art clinical studies, and communications regarding UTC's decision to fund those clinical studies. These communications speak to, amongst other issues, physicians' practices in treating PH-ILD with inhaled treprostinil and what UTC knew regarding such practices, which are relevant to invalidity and unenforceability of the '327 patent.
    - Liquidia notes that, unlike RFP Nos. 21-27 and 29-31 to which UTC has indicated a willingness to meet-and-confer, UTC has refused to produce documents to RFP No. 28. For the reasons above, the information sought in RFP No. 28 is relevant and Liquidia does not see any reason to not produce documents responsive to RFP No. 28.
- **RFP Nos. 32-35:**
  - Liquidia's position: UTC itself has argued that the '327 patent describes the INCREASE trial and that the results of that trial were integral to the novelty of

the '327 patent. Communications and documents relating to the INCREASE trial are thus relevant. Further, given that UTC sponsored the INCREASE trial and is required by the FDA to maintain documents on the INCREASE trial, these requests are not unduly burdensome.

- **RFP No. 36:**
  - Liquidia's position: The TETON trial is aimed at studying improvements in FVC and exacerbations in the lung disease underlying PH-ILD (*See, e.g.*, S.D. Nathan, et al., *BMJ Open Respir. Res.*, 9:e001310 (2022), available at https://bmjopenrespres.bmj.com/content/9/1/e001310.long), and thus is at least relevant to the validity of the '327 patent claims directed at FVC and exacerbations. Liquidia is willing to narrow this request to documents on the decision to conduct the TETON trial, including when that decision was made, studies or research relied on to justify the trial, research and development documents from the trial including interim results, protocols, investigator's brochures, clinical study reports, and posters.
- **RFP No. 37**:
  - Liquidia's position: The mechanisms of action of inhaled treprostinil in patients with PH-ILD, including on the very metrics claimed by the '327 patent (i.e., exercise capacity, 6MWD, FVC, NT-proBNP, exacerbations of ILD, and clinical worsening), inform at least the prior art and potential prior art and are directed at a narrow set of documents on mechanisms of action of specific metrics. Presumably for development and approval of Tyvaso for PH-ILD, UTC conducted testing on the mechanism of action or had mechanism of action documents that provide the rationale for measuring the effects of inhaled treprostinil on these outcome measures.
- **RFP Nos. 38-39, 46**:
  - Liquidia's position: These Requests are generally directed at communications between UTC and third-parties concerning administration of Tyvaso in patients with PH-ILD. Given public statements by Dr. Rothblatt in 2018, physicians were certainly using Tyvaso for PH-ILD before this time and were communicating with UTC about them. Such communications are relevant to prior art and UTC's knowledge of this prior art and invention
- **RFP Nos. 40-42**:
  - Liquidia's position: These requests generally seek information on research and development, including internal presentations and SAB and KOL meeting minutes, of treprostinil for PH-ILD. To the extent that UTC argues that these RFPs are captured by RFP No. 1, these RFPs seek non-overlapping documents with UTC's response to RFP No. 1.
- **RFP Nos. 43-44**:
  - Liquidia's position: These requests generally seek documents related to the NDA for Tyvaso® and Tyvaso® DPI. These Requests are obviously relevant. UTC has listed the '327 patent in the Orange Book for Tyvaso (*see, e.g.*, D.I. 8 (UTC Compl.) at ¶ 1, and repeatedly referenced its approval in its filings in this case. (*See, e.g.*, *Id.* at ¶ 12; D.I. 26 at 2). It is also no burden for UTC to produce its NDA documents since it must keep these documents for the FDA. Liquidia is

willing to limit this Request to anything in the NDA, IND, and correspondence with FDA related to PH-ILD.

- **RFP No. 45**:
  - Liquidia's position: The Tyvaso DPI Inhalation Device is relevant to, for example, Claims 11 and 14, including the construction of "pulsed inhalation device" and the validity of the '327 patent. Liquidia has requested only five devices, which presumably UTC has since Tyvaso DPI is marketed and sold, and has been since 2023.
- **RFP Nos. 47-57, 61-63**:
  - Liquidia's position: These requests collectively seek documents concerning market research, competition with Yutrepia, pricing strategies, contractual terms of the sale of UTC's treprostinil products, and financial projections that are all highly relevant to damages and UTC's allegations of irreparable harm. These requests are also narrow in scope, being limited to PH-ILD and Tyvaso®.
- **RFP No. 66**:
  - Liquidia's position: This Request seeks documents and things created, reviewed, or relied upon for the prosecution of the '327 patent. Liquidia has inequitable conduct claims in this matter, and thus, this Request at least is directly relevant to those claims.
- **RFP No. 67**:
  - Liquidia's position: While UTC agreed to produce documents to this Request, it cabined its response such that it "will not produce documents unrelated to the '327 patent." Many of the interrogatories may be broader than the '327 patent, including those that relate to damages. It further would be improper for UTC to rely on documents in its interrogatories that do not relate to the '327 patent and then not produce them. Please confirm you will produce all documents considered or relied upon to answer the Interrogatories.
- **RFP Nos. 68-75:**
  - Liquidia's position: These RFPs seek documents relating to license agreements which are integral to determinations of damages and secondary considerations of non-obviousness. In addition, RFP Nos. 68 and 70 seek documents relating to the Dreamboat inhalation device and license terms for the device, which are relevant to the "pulsed inhalation device" claims at issue as well as damages determinations.

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HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TYVASO safely and effectively. See full prescribing information for TYVASO.

TYVASO® (treprostinil) inhalation solution, for oral inhalation use
Initial U.S. Approval: 2002

----------RECENT MAJOR CHANGES----------
Warnings and Precautions (5.4) 05/2022

---------- INDICATIONS AND USAGE----------
Tyvaso is a prostacyclin mimetic indicated for the treatment of:
- Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). (1.1)
- Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%). (1.2)

----------DOSAGE AND ADMINISTRATION----------
- Use only with the Tyvaso Inhalation System. (2.1)
- Administer undiluted, as supplied. A single breath of Tyvaso delivers approximately 6 mcg of treprostinil. (2.1)
- Administer in 4 separate treatment sessions each day approximately 4 hours apart, during waking hours. (2.1)
- Initial dosage: 3 breaths (18 mcg) per treatment session. If 3 breaths are not tolerated, reduce to 1 or 2 breaths. (2.1)
- Dosage should be increased by an additional 3 breaths per treatment session at approximately 1- to 2-week intervals, if tolerated. (2.1)
- Titrate to target maintenance doses of 9 to 12 breaths per treatment session, 4 times daily. (2.1)

---------- DOSAGE FORMS AND STRENGTHS----------
Sterile solution for oral inhalation: 2.9 mL ampule containing 1.74 mg treprostinil (0.6 mg per mL). (3)

---------- CONTRAINDICATIONS ----------
None. (4)

---------- WARNINGS AND PRECAUTIONS ----------
- Tyvaso may cause symptomatic hypotension. (5.1)
- Tyvaso inhibits platelet aggregation and increases the risk of bleeding. (5.2)
- Tyvaso dosage adjustments may be necessary if inhibitors or inducers of CYP2C8 are added or withdrawn. (5.3, 7.3)
- May cause bronchospasm: Patients with a history of hyperreactive airway disease may be more sensitive. (5.4)

---------- ADVERSE REACTIONS ----------
Most common adverse reactions (≥4%) are cough, headache, nausea, dizziness, flushing, throat irritation, pharyngolaryngeal pain, diarrhea, and syncope. (6)

To report SUSPECTED ADVERSE REACTIONS, contact United Therapeutics Corp. at 1-866-458-6479 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 05/2022

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Pulmonary Arterial Hypertension

Tyvaso is indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%).

The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities.

While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration *[see Clinical Studies (14)]*.

1.2 Pulmonary Hypertension Associated with ILD

Tyvaso is indicated for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%) *[see Clinical Studies (14)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Usual Dosage in Adults

Tyvaso is intended for oral inhalation using the Tyvaso Inhalation System, which consists of an ultrasonic, pulsed delivery device and its accessories.

Tyvaso is dosed in 4 separate, equally spaced treatment sessions per day, during waking hours. Each treatment session will take 2 to 3 minutes. The treatment sessions should be approximately 4 hours apart.

Initial Dosage:

Therapy should begin with 3 breaths of Tyvaso (18 mcg of treprostinil) per treatment session 4 times daily. If 3 breaths are not tolerated, reduce to 1 or 2 breaths and subsequently increase to 3 breaths, as tolerated.

Maintenance Dosage:

Dosage should be increased by an additional 3 breaths per treatment session, 4 times daily at approximately 1- to 2-week intervals. Studies establishing effectiveness in patients with PAH and PH-ILD have used target doses of 9 to 12 breaths per treatment session, 4 times daily. If adverse effects preclude titration to target dose, Tyvaso should be continued at the highest tolerated dose.

If a scheduled treatment session is missed or interrupted, therapy should be resumed as soon as possible at the usual dose.

2.2 Administration

Tyvaso must be used only with the Tyvaso Inhalation System. Patients should follow the instructions for use for operation of the Tyvaso Inhalation System and for daily cleaning of the device components after the last treatment session of the day. To avoid potential interruptions in drug delivery because of equipment malfunction, patients should have access to a back-up Tyvaso Inhalation System device.

Do not mix Tyvaso with other medications in the Tyvaso Inhalation System. Compatibility of Tyvaso with other medications has not been studied.

The Tyvaso Inhalation System should be prepared for use each day according to the instructions for use. One ampule of Tyvaso contains a sufficient volume of medication for all 4 treatment sessions in a single day. Prior to the first treatment session, the patient should twist the top off a single Tyvaso ampule and squeeze the entire contents into the medicine cup. Between each of the 4 daily treatment sessions, the device should be capped and stored upright with the remaining medication inside.

At the end of each day, the medicine cup and any remaining medication must be discarded. The device must be cleaned each day according to the instructions for use.

Avoid skin or eye contact with Tyvaso solution. Do not orally ingest the Tyvaso solution.

3 DOSAGE FORMS AND STRENGTHS

Sterile solution for oral inhalation: 2.9 mL ampule containing 1.74 mg of treprostinil (0.6 mg per mL).

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Risk of Symptomatic Hypotension

Treprostinil is a pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, treatment with Tyvaso may produce symptomatic hypotension.

5.2 Risk of Bleeding

Tyvaso inhibits platelet aggregation and increases the risk of bleeding.

5.3 Effect of Other Drugs on Treprostinil

Co-administration of a cytochrome P450 (CYP) 2C8 enzyme inhibitor (e.g., gemfibrozil) may increase exposure (both C_{max} and AUC) to treprostinil. Co-administration of a CYP2C8 enzyme inducer (e.g., rifampin) may decrease exposure to treprostinil. Increased exposure is likely to increase adverse events associated with treprostinil administration, whereas decreased exposure is likely to reduce clinical effectiveness *[see Drug Interactions (7.3) and Clinical Pharmacology (12.3)]*.

5.4 Bronchospasm

Like other inhaled prostaglandins, Tyvaso may cause acute bronchospasm. Patients with asthma or chronic obstructive pulmonary disease (COPD), or other bronchial hyperreactivity, are at increased risk

for bronchospasm. Ensure that such patients are treated optimally for reactive airway disease prior to and during treatment with Tyvaso Inhalation Solution.

6 ADVERSE REACTIONS

The following potential adverse reactions are described in Warnings and Precautions (5):

- Decrease in systemic blood pressure *[see Warnings and Precautions (5.1)]*.
- Bleeding *[see Warnings and Precautions (5.2)]*.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Pulmonary Arterial Hypertension

In a 12-week, placebo-controlled study (TRIUMPH I) of 235 patients with PAH (WHO Group 1 and nearly all NYHA Functional Class III), the most commonly reported adverse reactions on Tyvaso included cough and throat irritation, headache, gastrointestinal effects, muscle, jaw or bone pain, dizziness, flushing, and syncope. Table 1 lists the adverse reactions that occurred at a rate of at least 4% and were more frequent in patients treated with Tyvaso than with placebo.

Table 1: Adverse Events in ≥4% of PAH Patients Receiving Tyvaso and More Frequent[a] than Placebo in TRIUMPH I

Adverse Event	Treatment n (%)	
	Tyvaso n=115	Placebo n=120
Cough	62 (54)	35 (29)
Headache	47 (41)	27 (23)
Throat Irritation / Pharyngolaryngeal Pain	29 (25)	17 (14)
Nausea	22 (19)	13 (11)
Flushing	17 (15)	1 (<1)
Syncope	7 (6)	1 (<1)

[a] More than 3% greater than placebo

The safety of Tyvaso was also studied in a long-term, open-label extension study in which 206 patients were dosed for a mean duration of 2.3 years, with a maximum exposure of 5.4 years. Eighty-nine percent (89%) of patients achieved the target dose of 9 breaths, 4 times daily. Forty-two percent (42%) achieved a dose of 12 breaths, 4 times daily. The adverse events during this chronic dosing study were qualitatively similar to those observed in the 12-week placebo-controlled trial.

In a prospective, observational study comparing patients taking Tyvaso (958 patient-years of exposure) and a control group (treatment with other approved therapies for PAH; 1094 patient-years), Tyvaso was associated with a higher rate of cough (16.2 vs. 10.9 per 100 patient-years), throat irritation (4.5 vs.

1.2 per 100 pt-years), nasal discomfort (2.6 vs. 1.3 per 100 pt-years), and hemoptysis (2.5 vs. 1.3 per 100 pt-years) compared to the control group.

Pulmonary Hypertension Associated with ILD

In a 16-week, placebo-controlled study (INCREASE) of 326 patients with PH-ILD (WHO Group 3), adverse reactions were similar to the experience in studies of PAH.

6.2 Post-Marketing Experience

The adverse reaction of angioedema has been identified during the post-approval use of Tyvaso. Because this reaction is reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.

7 DRUG INTERACTIONS

7.1 Bosentan

In a human pharmacokinetic study conducted with bosentan (250 mg/day) and an oral formulation of treprostinil (treprostinil diolamine), no pharmacokinetic interactions between treprostinil and bosentan were observed.

7.2 Sildenafil

In a human pharmacokinetic study conducted with sildenafil (60 mg/day) and an oral formulation of treprostinil (treprostinil diolamine), no pharmacokinetic interactions between treprostinil and sildenafil were observed.

7.3 Effect of Cytochrome P450 Inhibitors and Inducers

In vitro studies of human hepatic microsomes showed that treprostinil does not inhibit cytochrome P450 (CYP) isoenzymes CYP1A2, CYP2A6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, and CYP3A. Additionally, treprostinil does not induce cytochrome P450 isoenzymes CYP1A2, CYP2B6, CYP2C9, CYP2C19, and CYP3A.

Human pharmacokinetic studies with an oral formulation of treprostinil (treprostinil diolamine) indicated that co-administration of the cytochrome P450 (CYP) 2C8 enzyme inhibitor, gemfibrozil, increases exposure (both C_{max} and AUC) to treprostinil. Co-administration of the CYP2C8 enzyme inducer, rifampin, decreases exposure to treprostinil. It is unclear if the safety and efficacy of treprostinil by the inhalation route are altered by inhibitors or inducers of CYP2C8 *[see Warnings and Precautions (5.3)]*.

7.4 Effect of Other Drugs on Treprostinil

Drug interaction studies have been carried out with treprostinil (oral or subcutaneous) co-administered with acetaminophen (4 g/day), warfarin (25 mg/day), and fluconazole (200 mg/day), respectively, in healthy volunteers. These studies did not show a clinically significant effect on the pharmacokinetics of treprostinil. Treprostinil does not affect the pharmacokinetics or pharmacodynamics of warfarin. The pharmacokinetics of R- and S- warfarin and the international normalized ratio (INR) in healthy subjects given a single 25 mg dose of warfarin were unaffected by continuous subcutaneous infusion of treprostinil at an infusion rate of 10 ng/kg/min.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Limited case reports of treprostinil use in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. However, there are risks to the mother and the fetus associated with pulmonary arterial hypertension *(see Clinical Considerations)*. In animal studies, no adverse reproductive and developmental effects were seen for treprostinil at ≥9 and ≥145 times the human exposure when based on C_{max} and AUC, respectively, following a single treprostinil dose of 54 mcg.

The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Disease-associated maternal and embryo-fetal risk

Pulmonary arterial hypertension is associated with an increased risk of maternal and fetal mortality.

Data

Animal reproduction studies have been conducted with treprostinil via continuous subcutaneous administration and with treprostinil diolamine administered orally. In studies with orally administered treprostinil diolamine, no adverse effect doses for fetal viability/growth, fetal development (teratogenicity), and postnatal development were determined in rats. In pregnant rats, no evidence of harm to the fetus was observed following oral administration of treprostinil diolamine at the highest dose tested (20 mg/kg/day), which represents about 154 and 1479 times the human exposure, when based on C_{max} and AUC, respectively, following a single Tyvaso dose of 54 mcg. In pregnant rabbits, external fetal and soft tissue malformations and fetal skeletal malformation occurred. The dose at which no adverse effects were seen (0.5 mg/kg/day) represents about 9 and 145 times the human exposure, when based on C_{max} and AUC, respectively, following a single Tyvaso dose of 54 mcg. No treprostinil treatment-related effects on labor and delivery were seen in animal studies. Animal reproduction studies are not always predictive of human response.

8.2 Lactation

Risk Summary

There are no data on the presence of treprostinil in human milk, the effects on the breastfed infant, or the effects on milk production.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Clinical studies of Tyvaso did not include patients younger than 18 years to determine whether they respond differently from older patients.

8.5 Geriatric Use

Across clinical studies used to establish the effectiveness of Tyvaso in patients with PAH and PH-ILD, 268 (47.8%) patients aged 65 years and over were enrolled. The treatment effects and safety profile observed in geriatric patients were similar to younger patients. In general, dose selection for an elderly

patient should be cautious, reflecting the greater frequency of hepatic, renal, or cardiac dysfunction, and of concomitant diseases or other drug therapy.

8.6 Patients with Hepatic Insufficiency

Plasma clearance of treprostinil, delivered subcutaneously, was reduced up to 80% in subjects with mild-to-moderate hepatic insufficiency. Uptitrate slowly when treating patients with hepatic insufficiency because of the risk of an increase in systemic exposure which may lead to an increase in dose-dependent adverse effects. Treprostinil has not been studied in patients with severe hepatic insufficiency *[see Clinical Pharmacology (12.3)]*.

8.7 Patients with Renal Impairment

No dose adjustments are required in patients with renal impairment. Treprostinil is not cleared by dialysis *[see Clinical Pharmacology (12.3)]*.

10 OVERDOSAGE

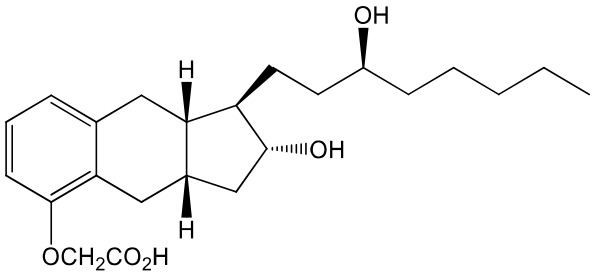
In general, symptoms of overdose with Tyvaso include flushing, headache, hypotension, nausea, vomiting, and diarrhea. Provide general supportive care until the symptoms of overdose have resolved.

11 DESCRIPTION

Tyvaso is a sterile formulation of treprostinil, a prostacyclin mimetic, intended for administration by oral inhalation using the Tyvaso Inhalation System. Tyvaso is supplied in 2.9 mL low density polyethylene (LDPE) ampules, containing 1.74 mg treprostinil (0.6 mg/mL). Each ampule also contains 18.9 mg sodium chloride, 18.3 mg sodium citrate dihydrate, 0.58 mg sodium hydroxide, 11.7 mg 1 N hydrochloric acid, and water for injection. Sodium hydroxide and hydrochloric acid may be added to adjust pH between 6.0 and 7.2.

Treprostinil is (1*R*,2*R*,3a*S*,9a*S*)-[[2,3,3a,4,9,9a-hexahydro-2-hydroxy-1-[(3*S*)-3-hydroxyoctyl]-1*H*-benz[*f*]inden-5-yl]oxy]acetic acid. Treprostinil has a molecular weight of 390.52 and a molecular formula of $C_{23}H_{34}O_5$.

The structural formula of treprostinil is:



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Treprostinil is a prostacyclin analogue. The major pharmacologic actions of treprostinil are direct vasodilation of pulmonary and systemic arterial vascular beds and inhibition of platelet aggregation.

12.2 Pharmacodynamics

In a clinical trial of 240 healthy volunteers, single doses of Tyvaso 54 mcg (the target maintenance dose per session) and 84 mcg (supratherapeutic inhalation dose) prolonged the corrected QTc interval by approximately 10 ms. The QTc effect dissipated rapidly as the concentration of treprostinil decreased.

12.3 Pharmacokinetics

Pharmacokinetic information for single doses of inhaled treprostinil was obtained in healthy volunteers in 3 separate studies. Treprostinil systemic exposure (AUC and C_{max}) post-inhalation was shown to be proportional to the doses administered (18 mcg to 90 mcg).

Absorption

In a 3-period crossover study, the bioavailability of 2 single doses of Tyvaso (18 mcg and 36 mcg) was compared with that of intravenous treprostinil in 18 healthy volunteers. Mean estimates of the absolute systemic bioavailability of treprostinil after inhalation were approximately 64% (18 mcg) and 72% (36 mcg).

Treprostinil plasma exposure data were obtained from 2 studies at the target maintenance dose, 54 mcg. The mean C_{max} at the target dose was 0.91 and 1.32 ng/mL with corresponding mean T_{max} of 0.25 and 0.12 hr, respectively. The mean AUC for the 54-mcg dose was 0.81 and 0.97 hr•ng/mL, respectively.

Distribution

Following parenteral infusion, the apparent steady state volume of distribution (V_{ss}) of treprostinil is approximately 14 L/70 kg ideal body weight.

In vitro treprostinil is 91% bound to human plasma proteins over the 330 to 10,000 mcg/L concentration range.

Metabolism and Excretion

Of subcutaneously administered treprostinil, only 4% is excreted unchanged in urine. Treprostinil is substantially metabolized by the liver, primarily by CYP2C8. Metabolites are excreted in urine (79%) and feces (13%) over 10 days. Five apparently inactive metabolites were detected in the urine, each accounting for 10 to 15% of the dose administered. Four of the metabolites are products of oxidation of the 3-hydroxyloctyl side chain and 1 is a glucuroconjugated derivative (treprostinil glucuronide).

The elimination of treprostinil (following subcutaneous administration of treprostinil) is biphasic, with a terminal elimination half-life of approximately 4 hours using a 2-compartment model.

Specific Populations

Hepatic Insufficiency

Plasma clearance of treprostinil, delivered subcutaneously, was reduced up to 80% in subjects presenting with mild-to-moderate hepatic insufficiency. Treprostinil has not been studied in patients with severe hepatic insufficiency *[see Use in Specific Populations (8.6)]*.

Renal Impairment

In patients with severe renal impairment requiring dialysis (n=8), administration of a single 1 mg dose of orally administered treprostinil pre- and post-dialysis resulted in $AUC_{0\text{-}inf}$ that was not significantly altered compared to healthy subjects *[see Use in Specific Populations (8.7)]*.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

A 2-year rat carcinogenicity study was performed with treprostinil inhalation at target doses of 5.26, 10.6, and 34.1 mcg/kg/day. There was no evidence for carcinogenic potential associated with treprostinil inhalation in rats at systemic exposure levels up to 35 times the clinical exposure at the target maintenance dose of 54 mcg. *In vitro* and *in vivo* genetic toxicology studies did not demonstrate any mutagenic or clastogenic effects of treprostinil. Treprostinil sodium did not affect fertility or mating performance of male or female rats given continuous subcutaneous infusions at rates of up to 450 ng treprostinil/kg/min. In this study, males were dosed from 10 weeks prior to mating and through the 2-week mating period. Females were dosed from 2 weeks prior to mating until gestational day 6.

Oral administration of treprostinil diolamine to Tg.rasH2 mice at 0, 5, 10, and 20 mg/kg/day in males and 0, 3, 7.5, and 15 mg/kg/day in females daily for 26 weeks did not significantly increase the incidence of tumors.

Treprostinil diolamine was tested *in vivo* in a rat micronucleus assay and did not induce an increased incidence of micronucleated polychromatic erythrocytes.

13.2 Animal Toxicology and/or Pharmacology

In a 2-year rat study with treprostinil inhalation at target doses of 5.26, 10.6, and 34.1 mcg/kg/day, there were more deaths (11) in the mid- and high-dose treprostinil groups during the first 9 weeks of the study, compared to 1 in control groups. At the high-dose level, males showed a higher incidence of inflammation in teeth and preputial gland, and females showed higher incidences of inflammation and urothelial hyperplasia in the urinary bladder. The exposures in rats at mid- and high-dose levels were about 15 and 35 times, respectively, the clinical exposure at the target maintenance dose of 54 mcg.

14 CLINICAL STUDIES

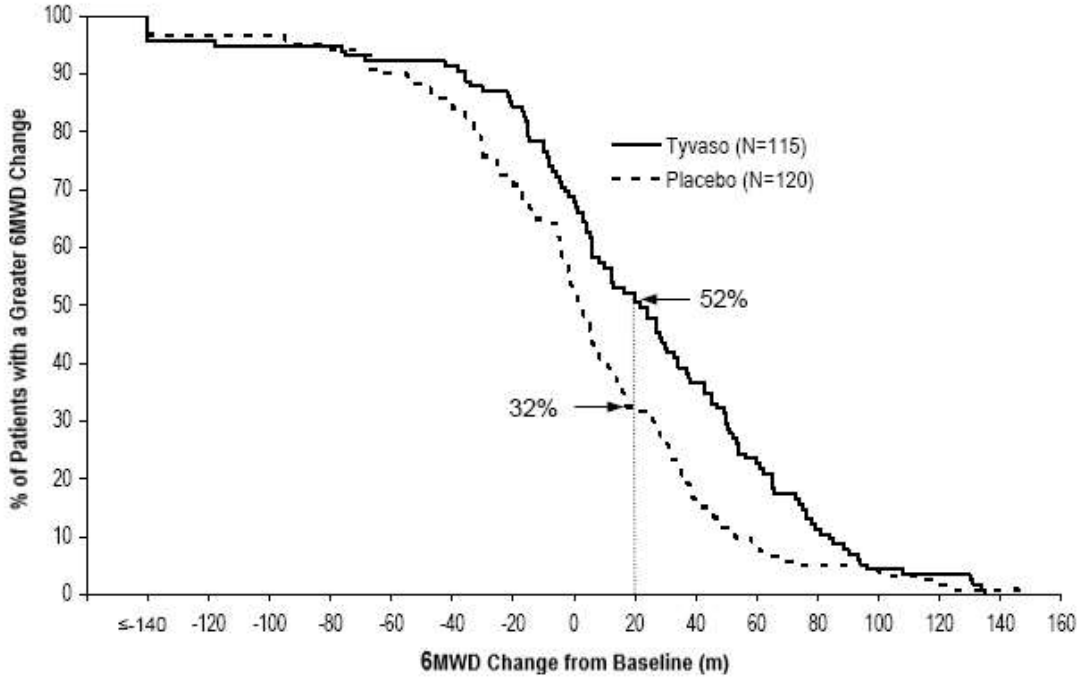
14.1 Pulmonary Arterial Hypertension (WHO Group 1)

TRIUMPH I, was a 12-week, randomized, double-blind, placebo-controlled, multicenter study of patients with PAH. The study population included 235 clinically stable subjects with PAH (WHO Group 1), nearly all with NYHA Class III (98%) symptoms who were receiving either bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase-5 inhibitor) for at least 3 months prior to study initiation. Concomitant therapy also could have included anticoagulants, other vasodilators (e.g., calcium channel blockers), diuretics, oxygen, and digitalis, but not a prostacyclin. These patients were administered either placebo or Tyvaso in 4 daily treatment sessions with a target dose of 9 breaths (54 mcg) per session over the course of the 12-week study. Patients were predominately female (82%), had the origin of PAH as idiopathic/heritable (56%), secondary to connective tissue diseases (33%) or secondary to HIV or previous use of anorexigens (12%); bosentan was the concomitant oral medication in 70% of those enrolled, sildenafil in 30%.

The primary efficacy endpoint of the trial was the change in 6-Minute Walk Distance (6MWD) relative to baseline at 12 weeks. 6MWD was measured at peak exposure (between 10 and 60 minutes after dosing), and 3 to 5 hours after bosentan or 0.5 to 2 hours after sildenafil. Patients receiving Tyvaso had a placebo-corrected median change from baseline in peak 6MWD of 20 meters at Week 12 ($p<0.001$). The distribution of these 6MWD changes from baseline at Week 12 were plotted across the range of observed values (Figure 1). 6MWD measured at trough exposure (defined as measurement of 6MWD at

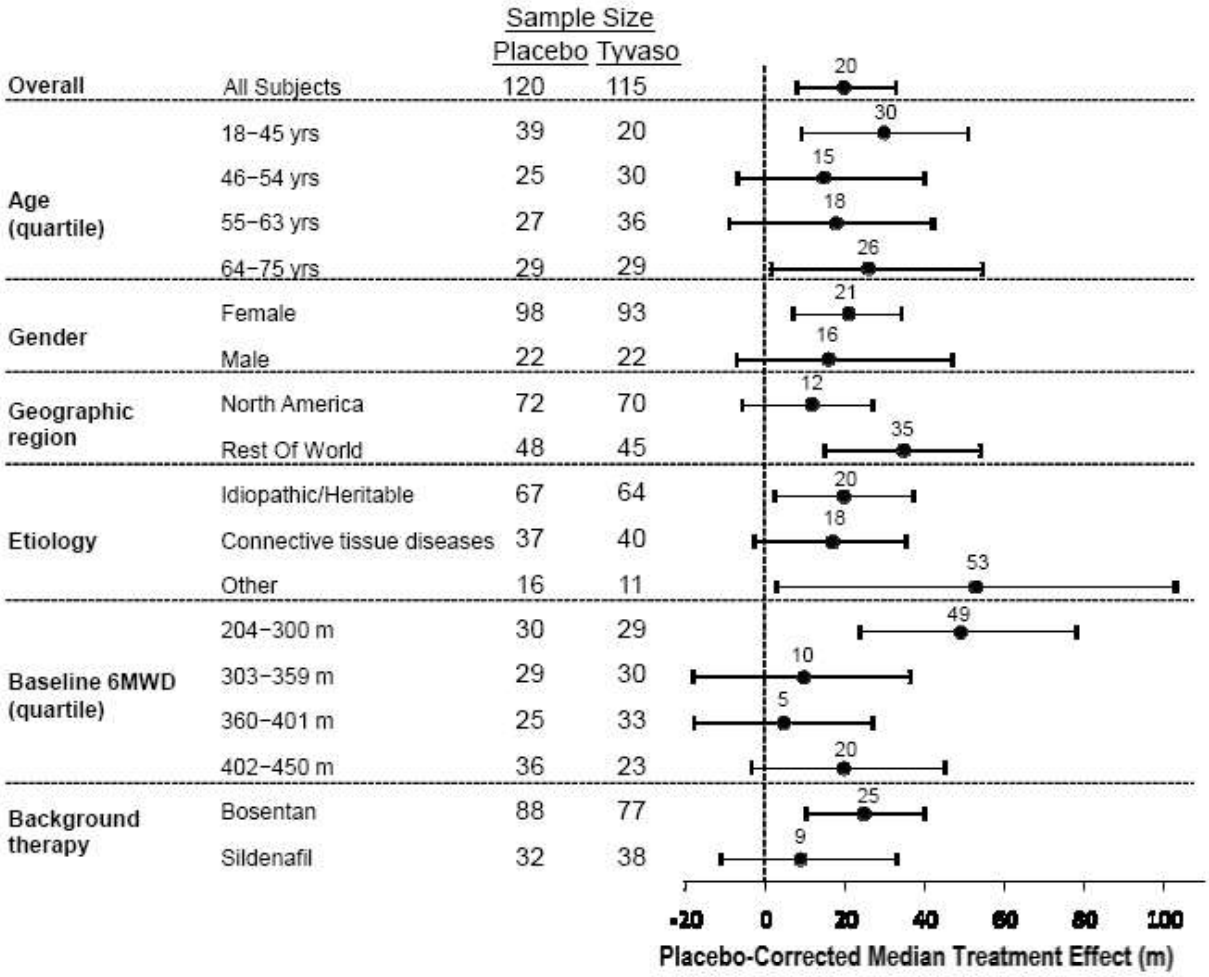
least 4 hours after dosing) improved by 14 meters. There were no placebo-controlled 6MWD assessments made after 12 weeks.

Figure 1: Distributions of 6MWD Changes from Baseline at Week 12 During Peak Plasma Concentration of Tyvaso



The placebo-corrected median treatment effect on 6MWD was estimated (using the Hodges-Lehmann estimator) within various subpopulations defined by age quartile, gender, geographic region of the study site, disease etiology, baseline 6MWD quartile, and type of background therapy (Figure 2).

Figure 2: **Placebo-Corrected Median Treatment Effect (Hodges-Lehmann Estimate with 95% CI) on 6MWD Change from Baseline at Week 12 During Peak Plasma Concentration of Tyvaso for Various Subgroups**



14.2 Long-term Treatment of PAH

In long-term follow-up of patients who were treated with Tyvaso in the pivotal study and the open-label extension (N=206), Kaplan-Meier estimates of survival at 1, 2, and 3 years were 97%, 91%, and 82%, respectively. These uncontrolled observations do not allow comparison with a control group not given Tyvaso and cannot be used to determine the long-term effect of Tyvaso on mortality.

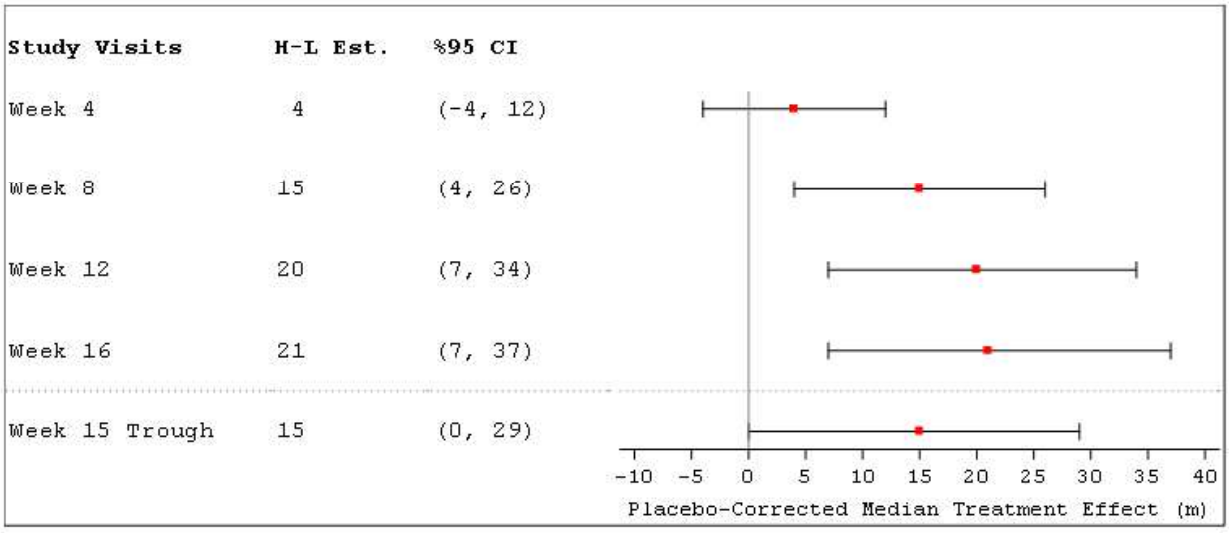
14.3 Pulmonary Hypertension Associated with ILD (WHO Group 3)

INCREASE was a 16-week, randomized, double-blind, placebo-controlled, multicenter study that enrolled 326 patients with PH-ILD. Enrolled study patients predominately had etiologies of idiopathic interstitial pneumonia (45%) inclusive of idiopathic pulmonary fibrosis, combined pulmonary fibrosis and emphysema (25%), and WHO Group 3 connective tissue disease (22%). The mean baseline 6MWD was 260 meters.

Patients in the INCREASE study were randomized (1:1) to either placebo or Tyvaso in 4 daily treatment sessions with a target dose of 9 breaths (54 mcg) per session and a maximum dose of 12 breaths (72 mcg) per session over the course of the 16-week study. Approximately 75% of patients randomized to Tyvaso titrated up to a dose of 9 breaths, 4 times daily or greater, with 48% of patients randomized to Tyvaso reaching a dose of 12 breaths, 4 times daily during the study.

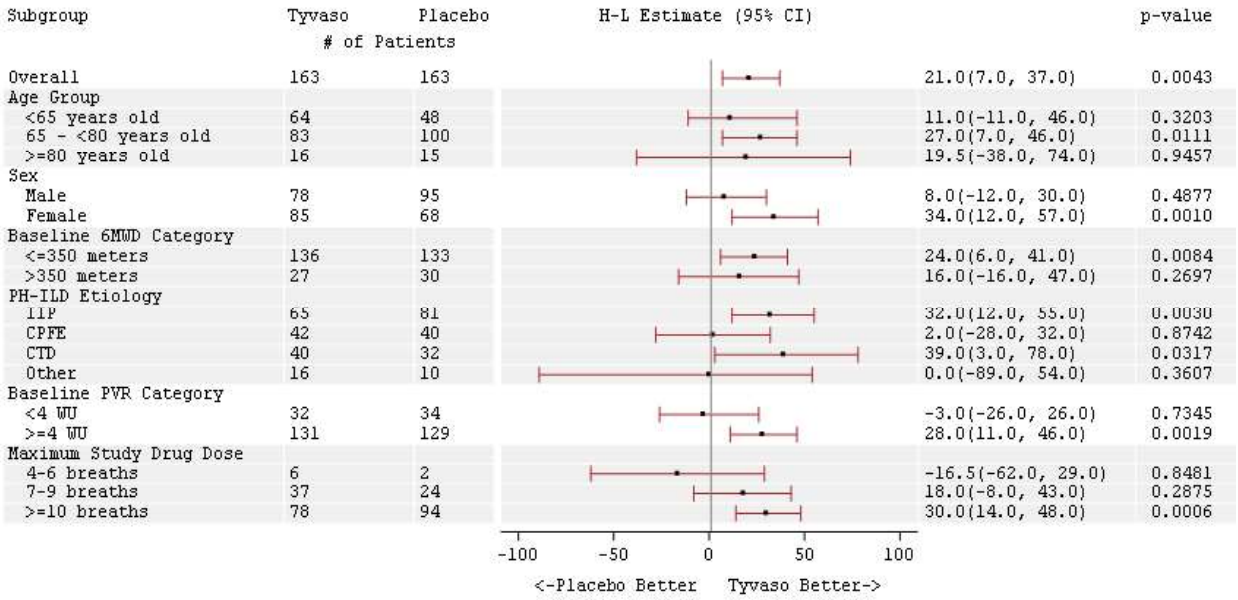
The primary efficacy endpoint was the change in 6MWD measured at peak exposure (between 10 and 60 minutes after dosing) from baseline to Week 16. Patients receiving Tyvaso had a placebo-corrected median change from baseline in peak 6MWD of 21 meters at Week 16 (p=0.004) using Hodges-Lehmann estimate (Figure 3).

Figure 3: Hodges-Lehmann Estimate of Treatment Effect by Visit for 6MWD at Peak Exposure (PH-ILD)



The treatment effect on 6MWD at Week 16 was consistent for various subgroups, including etiology of PH-ILD, disease severity, age, sex, baseline hemodynamics, and dose (Figure 4).

Figure 4: Forest Plot on Subgroup Analyses of Peak 6MWD (Meter) at Week 16 (PH-ILD)

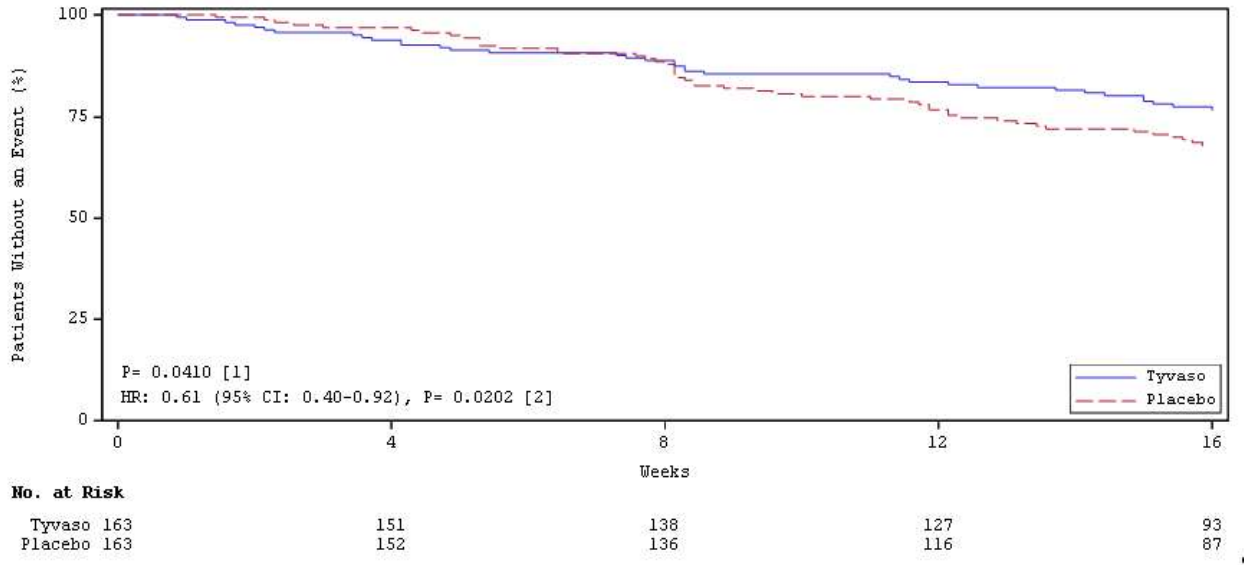


Time to clinical worsening in the INCREASE study was defined as the time of randomization until 1 of the following criteria were met: hospitalization due to a cardiopulmonary indication, decrease in 6MWD >15% from baseline directly related to PH-ILD at 2 consecutive visits and at least 24 hours apart, death (all causes), or lung transplantation. Treatment with Tyvaso in patients with PH-ILD resulted in numerically fewer hospitalizations. The numbers of reported deaths were the same for both treatment groups (Table 2). Overall, treatment with Tyvaso demonstrated a statistically significant increase in the time to first clinical worsening event (log-rank test p=0.041; Figure 5), and a 39% overall reduction in the risk of a clinical worsening event (HR=0.61 [95% CI; 0.40, 0.92]; Figure 5).

Table 2: Clinical Worsening Events (PH-ILD)

		Tyvaso n=163 n (%)	Placebo n=163 n (%)	HR (95% CI)
Clinical worsening		37 (22.7%)	54 (33.1%)	0.61 (0.40, 0.92)
First contributing event	**Hospitalization due to a cardiopulmonary indication**	18 (11.0%)	24 (14.7%)	
	Decrease in 6MWD >15% from baseline directly related to PH-ILD	13 (8.0%)	26 (16.0%)	
	Death (all causes)	4 (2.5%)	4 (2.5%)	
	Lung transplantation	2 (1.2%)	0	
First of each event	**Hospitalization due to a cardiopulmonary indication**	21 (12.9%)	30 (18.4%)	
	Decrease in 6MWD >15% from baseline directly related to PH-ILD	16 (9.8%)	31 (19.0%)	
	Death (all causes)	8 (4.9%)	10 (6.1%)	
	Lung transplantation	2 (1.2%)	1 (0.6%)	

Figure 5: Kaplan-Meier Plot of Time to Clinical Worsening Events (PH-ILD)



16 HOW SUPPLIED/STORAGE AND HANDLING

Tyvaso (treprostinil) inhalation solution is supplied in 2.9 mL clear LDPE ampules packaged as 4 ampules in a foil pouch. Tyvaso is a clear colorless to slightly yellow solution containing 1.74 mg treprostinil per ampule at a concentration of 0.6 mg/mL.

Ampules of Tyvaso are stable until the date indicated when stored in the unopened foil pouch at 20-25°C (68-77°F) with excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Once the foil pack is opened, ampules should be used within 7 days. Because Tyvaso is light-sensitive, unopened ampules should be stored in the foil pouch.

One ampule of Tyvaso should be used each day in the Tyvaso Inhalation System. After a Tyvaso ampule is opened and transferred to the medicine cup, the solution should remain in the device for no more than 1 day (24 hours). Any remaining solution should be discarded at the end of the day.

Tyvaso Inhalation System Starter Kit containing a 28-ampule carton of Tyvaso (7 foil pouches each containing four 2.9 mL ampules; each ampule contains 1.74 mg treprostinil [0.6 mg per mL]) and the Tyvaso Inhalation System. (NDC 66302-206-01)

Tyvaso Inhalation System Refill Kit containing a 28-ampule carton of Tyvaso (7 foil pouches each containing four 2.9 mL ampules; each ampule contains 1.74 mg treprostinil [0.6 mg per mL]) and accessories. (NDC 66302-206-02)

Tyvaso 4 Pack Carton with 1 foil pouch containing four 2.9 mL ampules. Each ampule contains 1.74 mg treprostinil (0.6 mg per mL). (NDC 66302-206-03)

Tyvaso Inhalation System Institutional Starter Kit containing a 4-ampule carton of Tyvaso (1 foil pouch containing four 2.9 mL ampules; each ampule contains 1.74 mg treprostinil [0.6 mg per mL]) and the Tyvaso Inhalation System. (NDC 66302-206-04)

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Instructions for Use).

Train patients in the administration process for Tyvaso, including dosing, Tyvaso Inhalation System set up, operation, cleaning, and maintenance, according to the instructions for use *[see Dosage and Administration (2.1, 2.2)]*.

To avoid potential interruptions in drug delivery because of equipment malfunction, patients should have access to a back-up Tyvaso Inhalation System device *[see Dosage and Administration (2.2)]*.

In the event that a scheduled treatment session is missed or interrupted, resume therapy as soon as possible *[see Dosage and Administration (2.1)]*.

If Tyvaso comes in contact with the skin or eyes, instruct patients to rinse immediately with water *[see Dosage and Administration (2.2)]*.

Tyvaso manufactured for:

United Therapeutics Corp.
Research Triangle Park, NC 27709

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,	)	
Plaintiff,	)	
v.	)	C.A. No. 23-975-RGA-SRF
LIQUIDIA TECHNOLOGIES, INC.,	)	HIGHLY CONFIDENTIAL
Defendant.	)	

PLAINTIFF'S RESPONSES AND OBJECTIONS TO DEFENDANT LIQUIDIA TECHNOLOGIES, INC.'S RULE 30(b)(6) NOTICE OF DEPOSITION OF UNITED THERAPEUTICS CORPORATION

Pursuant to Rules 26 and 30 of the Federal Rules of Civil Procedure, Plaintiff United Therapeutics Corporation ("UTC" or "Plaintiff"), by and through its undersigned counsel, hereby responds and objects to Defendant Liquidia Technologies, Inc.'s ("Liquidia" or "Defendant") Notice of Deposition of Plaintiff Pursuant to Fed. R. Civ. P. 30(b)(6) ("30(b)(6) Notice"), served on Oct. 9, 2024.

GENERAL OBJECTIONS

The following General Objections apply to and are incorporated by reference in each and every response to Defendant's 30(b)(6) Notice, whether or not specifically stated.

1. UTC objects to Defendant's 30(b)(6) Notice to the extent it purports to impose obligations different from or in addition to those imposed by the Federal Rules of Civil Procedure, the Local Rules of the United States District Court for the District of Delaware, and/or any standing orders of the Court.

2. UTC objects to each and every Topic for deposition listed in Defendant's 30(b)(6) Notice to the extent the Topic seeks information protected from discovery by the attorney-client

privilege, the work-product doctrine, and/or Federal Rule of Civil Procedure 26, and/or any other applicable privilege or immunity, including any jointly held privilege. UTC will not provide any such information. Any inadvertent disclosure of such protected information will not be deemed a waiver of any applicable protection.

3. UTC objects to each and every Topic in Defendant's 30(b)(6) Notice to the extent the Topic seeks expert testimony.

4. UTC objects to each and every Topic in Defendant's 30(b)(6) Notice to the extent the Topic seeks legal opinions, contentions, or conclusions

5. UTC objects to each and every Topic in Defendant's 30(b)(6) Notice to the extent the Topic seeks discovery as to matters or information not known or reasonably available to UTC

6. UTC objects to each and every Topic in Defendant's 30(b)(6) Notice to the extent the Topic seeks discovery as to matters or information that is more readily available through other means, including, but not limited to, written discovery.

7. UTC objects to each and every Topic for deposition in Defendant's 30(b)(6) Notice to the extent that it is overbroad, unduly burdensome, and/or seeks information that is not relevant to the claims or defenses of any party or is not proportional to the needs of the case.

8. UTC objects to each and every Topic for deposition listed in Defendant's 30(b)(6) Notice to the extent that it is ambiguous, vague, or otherwise fails to set forth with reasonable particularity the Topic for deposition.

9. UTC objects to each and every Topic for deposition listed in Defendant's 30(b)(6) Notice to the extent that it is cumulative to, or duplicative of, other discovery or information that has already been provided to Defendant.

10. UTC objects to each and every Topic for deposition listed in Defendant's 30(b)(6)

Notice to the extent that it seeks information or knowledge regarding research and development activities outside the scope of and/or not reasonably related to the inventions claimed in the Asserted Claims.

11. 11. UTC objects to each and every Topic for deposition listed in Defendant's 30(b)(6) Notice to the extent that it seeks information or knowledge that is not reasonably available to UTC and/or may be better sought from third parties. UTC is willing to meet and confer regarding the scope of information that is reasonably available to UTC.

12. UTC objects to each and every Topic for deposition listed in Defendant's 30(b)(6) Notice to the extent that it seeks information or knowledge related to research and development activities conducted by third-party entities and/or non-UTC employees, the details of which are not reasonably available to UTC. UTC is willing to meet and confer regarding the scope of information that is reasonably available to UTC.

13. These general objections are incorporated by reference in all individual responses set out below. Any failure to repeat all or any part of these objections in any specific response shall not constitute a waiver or relinquishment of such objection.

14. UTC objects generally to the definitions set forth in Defendant's 30(b)(6) Notice. UTC's responses to the Topics do not constitute representations or admissions that UTC agrees or adopts any of those definitions. The Specific Responses set forth below are based on UTC's interpretation of the language used in the Topics, and UTC reserves its right to amend or supplement its responses should Liquidia assert an interpretation that differs from UTC's interpretation.

15. UTC objects to the Definitions provided in Defendant's 30(b)(6) Notice to the extent they are internally inconsistent, thereby rendering the Topics vague and ambiguous.

16. UTC hereby incorporates by reference its objections to the Definitions provided by Liquidia, as set forth in:

a. Plaintiff's Responses and Objections to Defendant's First Set of Requests for Production (Nos. 1–75)

b. Plaintiff's Responses and Objections to Defendant's First Set of Interrogatories to Plaintiff (Nos. 1–6)

DEPOSITION TOPICS

TOPIC NO. 1: The administration/use of Tyvaso® prior to March 12, 2021, to patients with pulmonary hypertension associated with interstitial lung disease ("PH-ILD"), including UTC's knowledge concerning the use of Tyvaso® prior to March 12, 2021, to treat PH-ILD, the individuals at UTC who possessed such knowledge, communications and documents regarding such treatment with third parties, including patients, payors, doctors, hospitals, pharmacists, or other healthcare providers.

RESPONSE TO TOPIC NO. 1:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic on the grounds that it is vague, overly broad, and unduly burdensome, especially with respect to communications and documents regarding such treatment with third parties "including patients, payors, doctors, hospitals, pharmacists, or other healthcare providers." UTC objects to this topic as having scope that is not proportional to the needs of the case. If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control.

Subject to and without waiving the foregoing General and Specific Objections, UTC provisionally designates **Peter Smith** to testify regarding non-privileged, non-protected,

reasonably available facts concerning UTC's knowledge of off-label administration of Tyvaso® to PH-ILD patients by third-party medical providers prior to March 12, 2021.

TOPIC NO. 2: The administration/use of Remodulin® prior to March 12, 2021, to patients with PH-ILD, including UTC's knowledge concerning the use of Remodulin® prior to March 12, 2021, to treat PH-ILD, the individuals at UTC who possessed such knowledge, communications, and documents regarding such treatment with third parties, including payors, doctors, hospitals, pharmacists, or other health care providers.

RESPONSE TO TOPIC NO. 2:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic because it seeks information that is outside the scope of the subject matter recited by the Asserted Claims. In response to UTC's discovery requests, Liquidia has taken the position that that justifies refusing discovery. Under Liquidia's reasoning, this Topic is thus irrelevant to any claim or defense. This Topic is also overly broad, not relevant, and not proportional to the needs of the case. UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic on the grounds that it is vague, overly broad, and unduly burdensome, especially with respect to communications and documents regarding such treatment with third parties "including patients, payors, doctors, hospitals, pharmacists, or other healthcare providers." If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC

that is not within UTC's possession, custody, or control.

For the reasons set forth above, UTC will not designate a witness to testify regarding this Topic.

TOPIC NO. 3: The administration/use of Orenitram® prior to March 12, 2021 to patients with PH-ILD, including UTC's knowledge concerning the use of Orentitram® prior to March 12, 2021, to treat PH-ILD, the individuals at UTC who possessed such knowledge, communications and documents regarding such treatment with third parties, including payors, doctors, hospitals, pharmacists, or other health care providers.

RESPONSE TO TOPIC NO. 3:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic because it seeks information that is outside the scope of the subject matter recited by the Asserted Claims. In response to UTC's discovery requests, Liquidia has taken the position that that justifies refusing discovery. Under Liquidia's reasoning, this Topic is thus irrelevant to any claim or defense. This Topic is also overly broad, not relevant, and not proportional to the needs of the case. UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic on the grounds that it is vague, overly broad, and unduly burdensome, especially with respect to communications and documents regarding such treatment with third parties "including patients, payors, doctors, hospitals, pharmacists, or other healthcare providers." If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects

to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control.

For the reasons set forth above, UTC will not designate a witness to testify regarding this Topic.

TOPIC NO. 4: The reasons or decisions why UTC did not begin the INCREASE trial or any other Phase III clinical trial investigating Tyvaso® for the treatment of PH-ILD before February 3, 2017, including any business, financial, or legal reasons, and the persons involved in those decisions.

RESPONSE TO TOPIC NO. 4:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity, specifically insofar as it seeks testimony regarding "legal reasons." UTC objects to this Topic as it is irrelevant to the claims or defenses raised in this action. UTC objects to this Topic on the grounds that it is vague, overly broad, and unduly burdensome, especially to the extent it seeks testimony as to "any reasons or decisions[.]" This Topic is also overly broad, and not proportional to the needs of the case. If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic as vague, overly broad, and unduly burdensome, particularly as to the phrase "why UTC did not begin the INCREASE trial or any other Phase III clinical trial for Tyvaso® for the treatment of PH-ILD

before February 3, 2017[.]" UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control. UTC further objects to this Topic to the extent it is cumulative and/or duplicative, or seeks information more appropriately addressed through other forms of discovery, including by interrogatory(-ies), subpoena(s), and/or review of documents, or that will be addressed through expert reports and expert discovery.

Subject to and without waiving the foregoing General and Specific Objections, UTC provisionally designates **Peter Smith** to testify regarding the design, conduct, data, and results of the INCREASE trial.

TOPIC NO. 5: The reasons or decisions why UTC did not pursue a Phase III clinical trial investigating Remodulin® for the treatment of PH-ILD, including any business, financial, or legal reasons, and the persons involved in those decisions.

RESPONSE TO TOPIC NO. 5:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic because it seeks information that is outside the scope of the subject matter recited by the Asserted Claims. In response to UTC's discovery requests, Liquidia has taken the position that that justifies refusing discovery. Under Liquidia's reasoning, this Topic is thus irrelevant to any claim or defense. UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity, specifically insofar as it seeks testimony regarding "legal

reasons." UTC objects to this Topic on the grounds that it is vague, overly broad, and unduly burdensome, and not proportional to the needs of the case especially to the extent it seeks testimony as to "reasons or decisions" and the phrase "why UTC did not pursue a Phase III clinical trial investigating Remodulin® for the treatment of PH-ILD[.]" If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control. UTC further objects to this Topic to the extent it is cumulative and/or duplicative, or seeks information more appropriately addressed through other forms of discovery, including by interrogatory(-ies), subpoena(s), and/or review of documents, or that will be addressed through expert reports and expert discovery.

For the reasons set forth above, UTC will not designate a witness to testify regarding this Topic.

TOPIC NO. 6: The reasons or decisions why UTC did not pursue a Phase III clinical trial investigating Orenitram® for the treatment of PH-ILD, including any business, financial, or legal reasons, and the persons involved in those decisions.

RESPONSE TO TOPIC NO. 6:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic because it seeks information that is outside the scope of the subject matter recited by the Asserted Claims. In response to UTC's discovery requests, Liquidia

has taken the position that that justifies refusing discovery. Under Liquidia's reasoning, this Topic is thus irrelevant to any claim or defense. UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity, specifically insofar as it seeks testimony regarding "legal reasons." UTC objects to this Topic on the grounds that it is vague, overly broad, and unduly burdensome, and not proportional to the needs of the case, especially to the extent it seeks testimony as to "reasons or decisions" and the phrase "why UTC did not pursue a Phase III clinical trial investigating Orenitram® for the treatment of PH-ILD[.]" If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control. UTC further objects to this Topic to the extent it is cumulative and/or duplicative, or seeks information more appropriately addressed through other forms of discovery, including by interrogatory(-ies), subpoena(s), and/or review of documents, or that will be addressed through expert reports and expert discovery.

For the reasons set forth above, UTC will not designate a witness to testify regarding this Topic.

TOPIC NO. 7: All facts and circumstances concerning the addition of the treatment of PH-ILD to improve exercise ability as an indication to the prescribing information for Tyvaso DPI®, including, but not limited to, all communications and meetings between UTC and the FDA in connection with obtaining approval for this indication.

RESPONSE TO TOPIC NO. 7:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity, specifically insofar as it seeks testimony regarding "legal reasons." UTC objects to this Topic on the grounds that it is vague, overly broad, unduly burdensome, and not proportional to the needs of the case, especially to the extent it seeks testimony as to "all communications and meetings[.]" If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control. UTC further objects to this Topic to the extent it is cumulative and/or duplicative, or seeks information more appropriately addressed through other forms of discovery, including by interrogatory(-ies), subpoena(s), and/or review of documents, or that will be addressed through expert reports and expert discovery.

Subject to and without waiving the foregoing General and Specific Objections, UTC h[redacted] offered **Dean Bunce** who was deposed on October 29, 2024, and provided testimony at a reasonable level of detail regarding non-privileged, non-protected, reasonably available facts regarding the inclusion of a PH-ILD indication in UTC's NDA No. 214324 for Tyvaso DPI.

TOPIC NO. 8: To the extent UTC intends to present evidence that Tyvaso® and/or Tyvaso DPI® are a commercial success, all facts and circumstances concerning UTC's sales of Tyvaso® and Tyvaso DPI® for the treatment of PH-ILD, including but not limited to cost of goods, actual

sales, forecasted sales from May 2025 to May 2035, revenue, profits, the number of prescriptions, and refill rates.

RESPONSE TO TOPIC NO. 8:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic on the grounds that it is vague, overly broad, and unduly burdensome, and not proportional to the needs of the case, especially to the extent it seeks testimony as to "all facts and circumstances[.]" If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic as a contention topic, which is inappropriate for Rule 30(b)(6) deposition under District of Delaware authority. UTC objects to this Topic to the extent it seeks information irrelevant to the claims and defenses of this action. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control.

Subject to and without waiving the foregoing General and Specific Objections, UTC provisionally designates: (i) **Brian Patterson** to testify regarding non-privileged, non-protected, reasonably available facts regarding UTC's cost of goods sold and cost-related inputs to UTC's profits attributable to Tyvaso® and Tyvaso DPI® for the treatment of PH-ILD; and (ii) **Vijay Nainani** to testify regarding non-privileged, non-protected, reasonably available facts regarding actual sales, actual revenue, and revenue inputs to profit for Tyvaso and Tyvaso DPI for the treatment of PH-ILD.

TOPIC NO. 9: To the extent UTC intends to present evidence that Tyvaso® and/or Tyvaso DPI® are a commercial success, all facts and circumstances concerning UTC's market share of Tyvaso® and Tyvaso DPI® for the treatment of PH-ILD, including but not limited to patient uptake, patient adherence or continuation rates, the relevant market, competing products, and any internal or external evaluations of UTC's market position relative to competing products.

RESPONSE TO TOPIC NO. 9:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic on the grounds that it is vague, overly broad, and unduly burdensome, and not proportional to the needs of the case, especially to the extent it seeks testimony as to "all facts and circumstances[.]"If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic as a contention topic, which is inappropriate for Rule 30(b)(6) deposition under District of Delaware authority. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control.

Subject to and without waiving the foregoing General and Specific Objections, UTC provisionally designates: (i) **David Barton** to testify regarding non-privileged, non-protected, reasonably available facts regarding UTC's market analysis concerning payors; and (ii) a witness to testify regarding non-privileged, non-protected, reasonably available facts regarding UTC's market share for Tyvaso and Tyvaso DPI for the treatment of PH-ILD regarding patient uptake,

patient adherence or continuation rates, the relevant market, competing products, and any internal or external evaluations of UTC's market position relative to competing products.

TOPIC NO. 10: To the extent UTC intends to present evidence that Tyvaso® and/or Tyvaso DPI® are a commercial success, all facts and circumstances concerning UTC's marketing strategies for Tyvaso® and Tyvaso DPI® for the treatment of PH-ILD, including but not limited to monetary expenditures for marketing activities, advertising campaigns, promotional efforts, detailing healthcare professionals, promotion to patients and/or patient advocacy groups, and any related marketing documents or materials.

RESPONSE TO TOPIC NO. 10:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic on the grounds that it is vague, overly broad, and unduly burdensome, and not proportional to the needs of the case, especially to the extent it seeks testimony as to "all facts and circumstances[.]". If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic as a contention topic, which is inappropriate for Rule 30(b)(6) deposition under District of Delaware authority. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control.

Subject to and without waiving the foregoing General and Specific Objections, UTC will

designate a witness to testify regarding non-privileged, non-protected, reasonably available facts regarding UTC's marketing strategies for Tyvaso and Tyvaso DPI for the treatment of PH-ILD, including but not limited to monetary expenditures for marketing activities, advertising campaigns, promotional efforts, detailing healthcare professionals, promotion to patients and/or patient advocacy groups, and any related marketing documents or materials.

TOPIC NO. 11: To the extent UTC intends to present evidence that Tyvaso® and/or Tyvaso DPI® are a commercial success, efforts by UTC to educate prescribers, healthcare professionals, or other stakeholders about Tyvaso® and Tyvaso DPI® for the treatment of PH-ILD.

RESPONSE TO TOPIC NO. 11:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic on the grounds that it is vague, overly broad, unduly burdensome and not proportional to the needs of the case. If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic as a contention topic, which is inappropriate for Rule 30(b)(6) deposition under District of Delaware authority. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control.

Subject to and without waiving the foregoing General and Specific Objections, UTC will designate a witness to testify regarding non-privileged, non-protected, reasonably available facts

regarding UTC's efforts to educate prescribers, healthcare professionals, or other stakeholders about Tyvaso and Tyvaso DPI for the treatment of PH-ILD.

TOPIC NO. 12: To the extent UTC intends to present evidence that Tyvaso® and/or Tyvaso DPI® are a commercial success, all facts and circumstances concerning UTC's pricing and reimbursement strategies for Tyvaso® and Tyvaso DPI® for the treatment of PH-ILD, including but not limited to negotiations with respect to the placement of Tyvaso® and Tyvaso DPI® on formulary tiers, Wholesale Acquisition Cost ("WAC"), negotiations with payors, pharmacy benefit managers, and specialty pharmacies regarding pricing and reimbursement, pricing adjustments, patient assistance programs, discounts, rebates, and reimbursement rates.

RESPONSE TO TOPIC NO. 12:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic on the grounds that it is vague, overly broad, unduly burdensome, and not proportional to the needs of the case, especially to the extent it seeks testimony as to "all facts and circumstances[.]" If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic as a contention topic, which is inappropriate for Rule 30(b)(6) deposition under District of Delaware authority. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control.

Subject to and without waiving the foregoing General and Specific Objections, UTC provisionally designates **David Barton** to testify regarding UTC's pricing and reimbursement strategies for Tyvaso and Tyvaso DPI for the treatment of PH-ILD, including but not limited to negotiations with respect to the placement of Tyvaso and Tyvaso DPI on formulary tiers, wholesale acquisition cost ("WAC"), negotiations with payors, pharmacy benefit managers, and specialty pharmacies regarding pricing and reimbursement, pricing adjustments, patient assistance programs, discounts, rebates, and reimbursement rates.

TOPIC NO. 13: To the extent UTC intends to present evidence that Tyvaso® and/or Tyvaso DPI® are a commercial success, all licenses, settlement agreements, or other arrangements related to Tyvaso® or Tyvaso DPI® for the treatment of PH-ILD.

RESPONSE TO TOPIC NO. 13:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic on the grounds that it is vague, overly broad, unduly burdensome, and not proportional to the needs of the case, especially as related to "other arrangements[.]" If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic as a contention topic, which is inappropriate for Rule 30(b)(6) deposition under District of Delaware authority. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control.

For the reasons set forth above, UTC will not designate a witness to testify regarding this Topic.

TOPIC NO. 14: UTC's research and development activities concerning treatment regimens involving Tyvaso® or Tyvaso DPI® for the treatment of PH-ILD.

RESPONSE TO TOPIC NO. 14:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic on the grounds that it is vague, overly broad, unduly burdensome, and not proportional to the needs of the case, specifically in seeking information regarding the undefined term "treatment regimens." If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic as improperly compound to the extent comprises multiple subparts so as to comprise multiple distinct Topics and not properly propounded in a single Topic. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control.

Subject to and without waiving the foregoing General and Specific Objections, UTC provisionally designates **Peter Smith** to testify regarding non-privileged, non-protected, reasonably available facts regarding UTC's development of the FDA-approved dosing regimens for Tyvaso® and Tyvaso DPI® in PH-ILD.

TOPIC NO. 15: All research and development activities performed by or on behalf of UTC concerning the administration of Tyvaso® or Tyvaso DPI® to patients with PH-ILD, including all pre-clinical and clinical studies or trials.

RESPONSE TO TOPIC NO. 15:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic as vague, especially insofar as it seeks "[a]ll research and development activities[.]" UTC objects to this Topic on the grounds that it is overly broad, unduly burdensome, and not proportional to the needs of the case, especially insofar as it seeks "[a]ll research and development activities[.]" UTC objects to this Topic as improperly compound to the extent comprises multiple subparts so as to comprise multiple distinct Topics and not properly propounded in a single Topic. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control. UTC further objects to this Topic to the extent it is cumulative and/or duplicative, or seeks information more appropriately addressed through other forms of discovery, including by interrogatory(-ies), subpoena(s), and/or review of documents, or that will be addressed through expert reports and expert discovery.

Subject to and without waiving the foregoing General and Specific Objections, UTC provisionally designates **Peter Smith** to testify regarding non-privileged, non-protected, reasonably available facts concerning UTC's research and development of Tyvaso® and Tyvaso

DPI® for the treatment of PH-ILD.

TOPIC NO. 16: The design, conduct, data, and results of the INCREASE trial, including any publications concerning the INCREASE trial.

RESPONSE TO TOPIC NO. 16:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic as vague, especially insofar as it seeks "the design, conduct, data, and results of the INCREASE trial[.]" UTC objects to this Topic on the grounds that it is overly broad, unduly burdensome, and not proportional to the needs of the case. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control. UTC further objects to this Topic to the extent it is cumulative and/or duplicative, or seeks information more appropriately addressed through other forms of discovery, including by interrogatory(-ies), subpoena(s), and/or review of documents, or that will be addressed through expert reports and expert discovery.

Subject to and without waiving the foregoing General and Specific Objections, UTC provisionally designates **Peter Smith** to testify regarding non-privileged, non-protected, reasonably available facts concerning the design, conduct, data, and results of the INCREASE trial.

TOPIC NO. 17: The design, conduct, data, and results of the TETON trial, including

any publications concerning the TETON trial.

RESPONSE TO TOPIC NO. 17:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic because it seeks information that is outside the scope of the subject matter recited by the Asserted Claims. In response to UTC's discovery requests, Liquidia has taken the position that that justifies refusing discovery. Under Liquidia's reasoning, this Topic is thus irrelevant to any claim or defense. UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic as vague, especially insofar as it seeks "the design, conduct, data, and results of the TETON trial[.]" UTC objects to this Topic on the grounds that it is overly broad, unduly burdensome, and not proportional to the needs of the case. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control. UTC further objects to this Topic to the extent it is cumulative and/or duplicative, or seeks information more appropriately addressed through other forms of discovery, including by interrogatory(-ies), subpoena(s), and/or review of documents, or that will be addressed through expert reports and expert discovery.

For the reasons set forth above, UTC will not designate a witness to testify regarding this Topic.

TOPIC NO. 18: All communications, collaborations, contracts, or consultations between

UTC and third parties, including consultants, experts, clinicians, and researchers, regarding the development and use of Tyvaso® and Tyvaso DPI® for the treatment of PH-ILD.

RESPONSE TO TOPIC NO. 18:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic on the grounds that it is vague, overly broad, unduly burdensome, and not proportional to the needs of the case, especially to the extent it seeks information regarding "[a]ll communications, collaborations, contracts, or consultations[.]" If Liquidia has specific documents it wishes to ask UTC about within the scope of this Topic, it should identify them with specificity. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic as improperly compound to the extent comprises multiple subparts so as to comprise multiple distinct Topics and not properly propounded in a single Topic. UTC objects to this Topic as vague, especially insofar as it seeks "the development and use of Tyvaso® and Tyvaso DPI® for the treatment of PH-ILD." UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control. UTC further objects to this Topic to the extent it is cumulative and/or duplicative, or seeks information more appropriately addressed through other forms of discovery, including by interrogatory(-ies), subpoena(s), and/or review of documents, or that will be addressed through expert reports and expert discovery.

Subject to and without waiving the foregoing General and Specific Objections, UTC provisionally designates **Peter Smith** to testify regarding non-privileged, non-protected,

reasonably available facts concerning collaborations between UTC and third party clinicians and researchers regarding the development and use of Tyvaso® and Tyvaso DPI® for the treatment of PH-ILD.

TOPIC NO. 19: The factual basis for the statement made by UTC in its February 12, 2024 letter to the FDA that "the patents covering the new indication—the '793 patent, and U.S. Patent No. 11,826,327 ('the '327 patent')—did not trigger a 30-month stay." *See* LIQ_PH-ILD_00000847 at 852.

RESPONSE TO TOPIC NO. 19:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic because it seeks information that is outside the scope of the subject matter recited by the Asserted Claims. In response to UTC's discovery requests, Liquidia has taken the position that that justifies refusing discovery. Under Liquidia's reasoning, this Topic is thus irrelevant to any claim or defense. UTC objects to this Topic because it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity, specifically insofar as it seeks testimony regarding a letter sent by counsel. UTC objects to this Topic as vague insofar as it seeks the "factual basis" for a statement regarding the analysis of a law or regulation. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control. UTC objects to this Topic on the grounds that it is vague, overly broad, unduly burdensome, and not proportional to the needs of the case. UTC further objects to this Topic to the extent it is cumulative and/or duplicative, or seeks information more appropriately addressed through other forms of discovery, including by interrogatory(-ies), subpoena(s), and/or review of documents, or that will be

addressed through expert reports and expert discovery.

For the reasons set forth above, UTC will not designate a witness to testify regarding this Topic.

TOPIC NO. 20: The factual basis for statements made by UTC in its Patent Owner Response during the '793 Patent IPR on page 61 that "[t]he claimed invention of the '793 patent satisfies a long-felt unmet need in the treatment of pulmonary hypertension," because "inhaled treprostinil is indicated for a broader range of pulmonary hypertension patients than the therapeutics available at the time[, and] even for the treatment of pulmonary arterial hypertension, many patients found the existing therapies either intolerable or ineffective," and that "[i]nhaled treprostinil is currently approved for pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease." *See* LIQ_PH-ILD_00000110 at 180.

RESPONSE TO TOPIC NO. 20:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic because it seeks information that is outside the scope of the subject matter recited by the Asserted Claims. In response to UTC's discovery requests, Liquidia has taken the position that that justifies refusing discovery. Under Liquidia's reasoning, this Topic is thus irrelevant to any claim or defense. UTC further objects to this Topic because is seeks information related to the '793 patent IPR, a separate legal proceeding involving a separate patent on which Liquidia has already been afforded the opportunity to conduct substantial discovery, including depositions. *See, e.g.*, *Liquidia Technologies, Inc. v. United Therapeutics Corp*, IPR2021-00406 (P.T.A.B). UTC objects to this Topic to the extent it seeks discovery that is

cumulative and/or duplicative of deposition testimony and other discovery obtained by Liquidia during the '793 Patent IPR. UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity, specifically insofar as it seeks testimony regarding a document filed in litigation counsel. UTC objects to this Topic as vague insofar as it seeks the "factual basis" for a statement regarding the analysis of a law or regulation. UTC objects to this Topic on the grounds that it is overly broad, unduly burdensome, and not proportional to the needs of the case. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control. UTC further objects to this Topic to the extent it is cumulative and/or duplicative, or seeks information more appropriately addressed through other forms of discovery, including by interrogatory(-ies), subpoena(s), and/or review of documents, or that will be addressed through expert reports and expert discovery.

For the reasons set forth above, UTC will not designate a witness to testify regarding this Topic.

TOPIC NO. 21: The factual basis for the following statements made by Martine A. Rothblatt during UTC's FQ1 2018 Earnings Call concerning the use of Tyvaso®: "both through the effort of our medical affairs group over the years in supporting investigator-sponsored studies and through the kindness and generosity of certain payers around the country who have gone ahead and upon the initiative of their physicians, were able to enable some WHO Group III patients to benefit, there were unmistakable signals the some of the leading physicians in this field. I called out one of them on the call, Dr. Waxman, but there are many others, who said to UT, 'This drug works.' In fact, they believe that this drug works even better in that indication than in the Group I indication in terms of, at least, the exercise ability that they saw in their patients, discounting any

placebo effects that might be involved. So with that kind of data, some of which has been presented in posters and maybe even publications -- I don't know, but I've definitely seen posters, we went ahead and then had the statistics to power of the study for statistical significance, the one in the ILD population and the other in the COPD population, which are 2 distinct populations." LIQ_PH-ILD_00000001 at 10.

RESPONSE TO TOPIC NO. 21:

UTC incorporates the Preliminary Statement, General Objections, Objections to Definitions, and Objections to Instructions by reference as if fully stated herein.

UTC objects to this Topic to the extent it seeks information protected from discovery by the attorney-client privilege, the work-product doctrine, and/or any other privilege or immunity. UTC objects to this Topic to the extent it seeks discovery of information that is subject to confidentiality obligations to third parties. UTC objects to this Topic to the extent it seeks discovery from UTC that is not within UTC's possession, custody, or control. UTC further objects to this Topic to the extent it is cumulative and/or duplicative, or seeks information more appropriately addressed through other forms of discovery, including by interrogatory(-ies), subpoena(s), and/or review of documents, or that will be addressed through expert reports and expert discovery.

Subject to and without waiving the foregoing General and Specific Objections, UTC has offered **Dean Bunce** who was deposed on October 29, 2024, and provided testimony at a reasonable level of detail regarding non-privileged, non-protected, reasonably available facts regarding UTC's present knowledge of the factual basis for the identified statements by Martine A. Rothblatt during UTC's May 2, 2018 FQ1 2018 Earnings call concerning the use of Tyvaso. *See* LIQ_PH-ILD_00000001.

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CERTIFICATE OF SERVICE

I hereby certify that on November 1, 2024, copies of the foregoing were caused to be served upon the following in the manner indicated:

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